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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 79-485

ELI LILLY AND COMPANY,
Petitioner

v.

DOUGLAS M. COSTLE, ADMINISTRATOR,
ENVIRONMENTAL PROTECTION AGENCY

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Eli Lilly and Company petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case.

OPINIONS BELOW

The opinion of the Court of Appeals (App. A, *infra*) is reported in 598 F.2d 637. The decision of the Administrator of the Environmental Protection Agency is set forth in regulations published at 43 *Fed. Reg.* 17775 (App. C, *infra*).

JURISDICTION

The judgment of the Court of Appeals (App. B, *infra*) was entered on May 7, 1979. A timely petition for re-

hearing was denied on June 25, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

1. Whether under Section 4 of the Administrative Procedure Act EPA was required to provide notice and an opportunity for public comment before promulgating final regulations which differed substantially from the "interim final" regulations, especially where the Agency had generated a new and more extensive base of data not previously disclosed for public comment?

2. Assuming that EPA was not required to give notice and provide opportunity for public comment, whether the court in carrying out its review of the regulations should defer to those determinations by the Agency which were based on new data?

3. Again assuming that EPA was not required to give notice and provide opportunity for public comment, whether the reviewing court should conduct its own *de novo* review of new data and information, and impute certain determinations to the Agency, where the Agency's determinations are either nonexistence or inadequate to deal with the issues in dispute?

STATUTE INVOLVED

Sections 4(b)(3) and (c) of the Administrative Procedure Act, 5 U.S.C. § 553(b)(3), (c), provide in pertinent part:

§ 553. Rule making

* * * *

(b) General notice of proposed rule making shall be published in the Federal Register . . . . The notice shall include—

* * * *

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

* * * *

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments . . . .

STATEMENT

Section 301(b) of the Federal Water Pollution Control Act, as amended, 33 U.S.C. § 1311(b), authorizes the Environmental Protection Agency ("EPA" or "Agency") to issue regulations establishing effluent limitations for classes and categories of industrial point sources. Section 304(b), 33 U.S.C. § 1314(b), requires EPA to establish guidelines for the purpose of adopting such effluent limitation regulations. *See E. I. du Pont de Nemours & Co.* v. *Train*, 430 U.S. 112 (1977).

On November 1, 1976, EPA promulgated "interim final regulations" for the Pesticide Chemicals Manufacturing Point Source Category. 41 *Fed. Reg.* 48087. The interim final regulations established effluent limitations for existing sources implementing the first-stage requirement of Section 301(b) for the application of best practicable control technology currently available by July 1, 1977.[1]

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[1] EPA did not publish the regulations in proposed form. Citing an order of the United States District Court for the District of Columbia, EPA determined that the publication of proposed regulations was not practicable and, therefore, promulgated immediately effective "interim final regulations". 41 *Fed. Reg.* at 48088.

The Act also authorizes EPA to establish effluent limitations implementing the second-stage requirement of the Act, best available technology economically achievable. *See E. I. du Pont de Nemours & Co.* v. *Train*, 430 U.S. 112, 121 (1977). EPA decided to propose those regulations separately and at a later date. 41 *Fed. Reg.* at 48091.

Petitions for review of the interim final regulations were filed in the United States Court of Appeals for the First Circuit by BASF Wyandotte Corporation and five other companies on January 24, 1977. Subsequently filed petitions for review were transferred to that court. Eli Lilly did not file a petition for review of the interim final regulations.

EPA solicited comments on the interim final regulations. 41 *Fed. Reg.* at 48088. Comments on the interim final regulations were filed by a number of persons, including various manufacturers of pesticides. App. C, *infra*, 82a. Eli Lilly did not comment on the interim final regulations.

On April 25, 1978, EPA promulgated final regulations for the Pesticide Chemicals Manufacturing Point Source Category. 43 *Fed. Reg.* 17775.[2] On July 18, 1978, Eli Lilly filed a petition for review of the final regulations in the United States Court of Appeals for the Seventh Circuit. The petition was thereafter transferred to the United States Court of Appeals for the First Circuit.

Both the interim final and the final regulations established effluent limitations on the discharge of pesticide chemicals, five-day biochemical oxygen demand ("BOD_5"), and chemical oxygen demand ("COD"). The effluent limitations are expressed in terms of pounds of pollutants discharged for each thousand pounds of pesticide chemical manufactured ("lbs./1000 lbs.") and its metric equivalent ("kg./kkg."). Both a daily maximum discharge level and a maximum average discharge level over a 30-day period are specified.

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[2] The final regulations were amended subsequently to limit the application of the effluent limitations for the discharge of pesticide chemicals to 49 specified pesticides. 43 *Fed. Reg.* 44845 (Sept. 29, 1978).

The interim final regulations established effluent limitations for three separate subcategories of facilities producing organic pesticides: halogenated organic pesticides (Subcategory A), organo-phosphorous pesticides (Subcategory B), and organo-nitrogen pesticides (Subcategory C). Significantly different effluent limitations were prescribed for each subcategory,[3] and different data were used in deriving the effluent limitations for each subcategory. 41 *Fed. Reg.* at 48089-90. Eli Lilly manufactures an organo-nitrogen pesticide, trifluralin, at its Lafayette, Indiana plant.[4]

The final regulations collapsed the separate effluent limitations for the three categories into a single subcategory of organic pesticides and established a uniform set of effluent limitations for all organic pesticides. 40 C.F.R. § 455.22, App. C, *infra*, 105a.

The final effluent limitations for the collapsed subcategory of organic pesticides are substantially more stringent than the effluent limitations established by the interim final regulations for organo-nitrogen pesticides, including trifluralin:

	Interim Final (41 *Fed. Reg.* at 48090)		Final (40 C.F.R. § 455.22, App. C, *infra*, 105a)	
	30-Day Average	Daily Maximum	30-Day Average	Daily Maximum
Pesticides	0.0071 lbs./1000 lbs.	0.016 lbs./1000 lbs.	0.0018 lbs./1000 lbs.	0.01 lbs./1000lbs.
BOD_5	8.6 lbs./1000 lbs.	15.1 lbs./1000 lbs.	1.4 lbs./1000 lbs.	7.4 lbs./1000 lbs.
COD	21.1 lbs./1000 lbs.	30.4 lbs./1000 lbs.	9.0 lbs./1000 lbs.	13.0 lbs./1000 lbs.

[3]

	30-Day Average		
	COD	BOD5	Pesticides
Halogenated Organic	21.2 lbs./1000 lbs.	8.7 lbs./1000 lbs.	0.0031 lbs./1000 lbs.
Organo-Phosphorus	11.9 lbs./1000 lbs.	1.5 lbs./1000 lbs.	0.0018 lbs./1000 lbs.
Organo-Nitrogen	21.1 lbs./1000 lbs.	8.6 lbs./1000 lbs.	0.0071 lbs./1000 lbs.

(41 *Fed. Reg.* at 48089-90)

[4] Trifluralin is the only one of the 49 pesticides covered by the amended regulations which is produced by Eli Lilly. *See* Note 2, *supra*.

The data used in deriving the final effluent limitations for the collapsed subcategory were different from those used to derive the interim final effluent limitations for the organo-nitrogen pesticide subcategory.

In the preamble and appendix to the final regulations, EPA described the "major changes" in the regulations and the "expanded data base" upon which those major changes were premised. App. C, *infra*, 63a-67a, 87a-89a. One of the major changes described was the collapsing of the organic pesticide subcategories. EPA stated that the revisions to the regulations, including the elimination of subcategories, were based on the expanded data base and the Agency's reexamination of the data. App. C, *infra*, 64a. EPA further stated that the decision not to differentiate among different organic pesticides and to eliminate the interim subcategories was based on new data indicating that the "quantities of pollutants in the effluents of those plants with the properly operated model technologies installed were similar regardless of the organic pesticide chemicals manufactured" and that "the waste waters of all organic pesticide chemicals can be treated or controlled to the levels documented in the Agency's data base." App. C, *infra*, 64a.

No opportunity was afforded for comment on the major changes in the final regulations or on the new data on which those changes were based. Petitioners argued in the Court of Appeals that EPA should have issued notice for public comment on the proposed revisions, on the rationale for the revisions, and on the new, expanded data base said to support the revised regulations. Eli Lilly argued that it had not commented on the interim final regulations or filed a petition for review of those regulations because it considered them reasonable as applied to its only pesticide manufacturing plant at Lafayette, Indiana; thus, Eli Lilly contended that, by making the final regulations substantially more

stringent without notice to allow public comment, EPA deprived Eli Lilly of an opportunity to comment on the regulations and the basis for those regulations.

In its decision the court of appeals stated the following principle to be applied in determining whether EPA had complied with the Administrative Procedure Act ("APA"):

> Even substantial changes in the original plan may be made so long as they are "in character with the original scheme" and "a logical outgrowth" of the notice and comment already given. [598 F.2d at 642; App. A, *infra*, 7a (citation omitted).]

The court held that the "essential inquiry is whether the commenters have had a fair opportunity to present their views on the contents of the final plan" and whether, "given a new opportunity to comment, commenters would not have their first occasion to offer new and different criticisms which the Agency might find convincing". *Id.* at 642; App. A, *infra*, 7a-8a (footnote and citation omitted).

The court of appeals first dealt with EPA's determination to combine the three interim final subcategories for organic pesticides into a single subcategory. The court noted EPA had acted contrary to industry comments, which had criticized the interim final regulations and which had urged EPA to expand the number of subcategories. *Id.* at 643; App. A, *infra*, 9a. The court reasoned that it "should be clear to commenters when they criticize a regulatory scheme that if the agency accepts those criticisms, a new scheme will be substituted" and the "commenters cannot claim they had no notice to propose and discuss alternatives". *Id.* at 643; App. A, *infra*, 9a-10a. "[T]hough EPA's solution was not the one for which industry argued, it was suggested by and, in part, a logical outgrowth of industry's comments." *Id.* at 643; App. A, *infra*, 10a. Therefore, the court concluded that EPA was not required to give notice

of the decision to eliminate subcategories for organic pesticides and the industry was not entitled to comment thereon.

"For the same reasons," the court of appeals rejected the contention that EPA should have allowed further opportunity to comment on its determination that all pesticides can be treated to a single level because the possibility of that determination had been "clearly signalled in the interim regulations" since the "industry's comments plainly suggested that treatability ought to be taken into account." *Id.* at 644; App. A, *infra*, 11a (footnote omitted). Therefore, the court concluded that EPA was not required to permit comment on its determination or on the data and assumptions underlying that determination.

The court of appeals also upheld EPA's failure to allow comment on the new data relied upon by EPA and on the inferences from those data which led EPA to make major changes in the regulations:

> We must decide whether using new data that reduced the effluent limits for many of the producers deprived the public of a fair opportunity to present views on the final data base. If the data used and disclosed for the interim regulations presented the issues for comment, then there is no need to seek new comment even though significant quantitative differences result. [*Id.* at 645; App. A, *infra*, 13a.]

The court concluded that the disclosure of information with the interim final regulations permitted the industry to comment "on the importance of different processes, products, and volumes" and "to collect data at their own plants, analyze it, and submit it to EPA." *Id.* at 645; App. A, *infra*, 14a. "[W]e think it was far more important for EPA to solicit comments on how it intended to collect and use data than on the data itself". *Id.* at 645; App. A, *infra*, 15a. Therefore, the court concluded that EPA's reliance on the new data did not require the issuance of a further notice for public comment.

In reviewing the regulations and the determinations underlying the regulations, the court of appeals deferred to the expertise of the Agency and imposed a "heavy burden" on petitioners of persuading the court that EPA had erred. *Id.* at 649-50, 652; App. A, *infra*, 23a-24a, 28a. In the absence of an agency determination during the rulemaking process on issues raised by the petitioners, the court of appeals conducted its own review of the record or assumed that EPA had given appropriate consideration to the matter. Id. at 649, 656 nn. 34, 35 & 37; App. A, *infra*, 22a, 37a nn. 34 & 35, 38a-39a n. 37.

REASONS FOR GRANTING THE PETITION

I. THE ISSUES PRESENTED TO THIS COURT ARE IMPORTANT ISSUES WHICH SHOULD BE RESOLVED BY THE COURT TO PROVIDE GUIDANCE TO THE COURTS OF APPEALS AND TO THE ADMINISTRATIVE AGENCIES.

This case raises important issues which have not previously been addressed by this Court and the resolution of which is necessary in order to provide guidance to the courts of appeals and to the administrative agencies. The courts of appeals have had to deal increasingly with the notice-and-comment requirements of the APA. *See, e.g., National Crushed Stone Association* v. *Environmental Protection Agency*, 601 F.2d 111 (4th Cir. 1979); *Weyerhaeuser Corp.* v. *Costle*, 590 F.2d 1011 (D.C. Cir. 1978); *United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977); *American Iron and Steel Institute* v. *Environmental Protection Agency*, 568 F.2d 284 (3d Cir. 1977); *American Frozen Food Institute* v. *Train*, 539 F.2d 107 (D.C. Cir. 1976).

There is a high degree of probability that the issue will arise even more frequently in the future. For example, pursuant to an amended Consent Decree entered by the United States District Court for the District of

Columbia, EPA is obligated to promulgate regulations establishing effluent limitations and other requirements for thirty-four major industries by May 1981. *Natural Resources Defense Council* v. *Costle*, 12 E.R.C. 1833 (D.D.C. 1979), *appeal docketed*, No. 79-1473 (D.C. Cir. May 9, 1979). In implementing that obligation, the Agency has initiated the practice of proposing regulations which broadly suggest that it will consider alternatives to the proposal and which clearly indicate that it will compile additional information prior to promulgating final regulations. *See* 44 *Fed. Reg.* 38745, 38764, 38765, 38766 (July 2, 1979) (proposed regulations for the leather tanning industry). This Court should resolve the conflict among the courts of appeals and provide guidance to the Agency and the courts of appeals as to the Agency's obligation under the APA to issue notice for public comment on substantially revised regulations based on new or additional data and to the courts of appeals on the appropriate role of the reviewing court when regulations are based in part on such new data.

II. THE FIRST CIRCUIT'S DETERMINATION THAT THE ADMINISTRATOR COMPLIED WITH THE NOTICE-AND-COMMENT REQUIREMENT OF THE APA CONFLICTS WITH THE DECISIONS OF OTHER COURTS OF APPEALS AND IS INCORRECT.

A. The Regulations Were Substantially Changed on the Basis of New Data.

The final regulations for the single, collapsed organic pesticide subcategory are substantially more stringent than the interim final regulations for the organo-nitrogen pesticide subcategory and are premised on an expanded and different data base. The percentage by which the interim final regulations as applied to waste water from the manufacture of trifluralin and other organo-nitrogen pesticides were reduced is shown in the following table:

Reduction in Effluent Limitations
From Interim Final to Final Regulations

	30-Day Average	Daily Maximum
Pesticides	−75 percent	−47 percent
BOD_5	−84 percent	−51 percent
COD	−57 percent	−57 percent

These major changes in the interim final effluent limitations were premised on an "expanded data base" (App. C, *infra*, 64a, 67a) and EPA's "reexamination" of the regulations in light of that expanded data base (App. C, *infra*, 87a-88a). As noted by the court of appeals, the expanded data base resulting from EPA's "further research" was the justification for EPA's critical determination that the waste waters of all pesticide plants can be treated to the same level, for EPA's elimination of the interim final subcategories for organic pesticides, and for EPA's reduction of the effluent limitations. 598 F.2d at 643; App. A, *infra*, 9a. A particularly important basis for the EPA determination was data collected on existing carbon treatment plants by the Agency's contractor, ESE, after promulgation of the interim final regulations. As emphasized by the First Circuit, "[i]f ESE's work is not reliable, then the final limitations cannot stand". *Id.* at 646; App. A, *infra*, 16a. EPA also relied on its new examination of literature on treatment by carbon adsorption and hydrolysis,[5] on laboratory studies conducted by ESE, and on other data compiled and evaluations made subsequent to the publication of the interim final regulations. EPA did not issue public notice inviting comment on the expanded data base for the

[5] These two types of treatment were identified by EPA as the technologies whose use would allow the effluent limitations for pesticides to be met. *Id.* at 651; App. A, *infra*, 28a. The court of appeals' opinion includes a description of these technologies. *Id.* at 651; App. A, *infra*, 27a-28a.

substantially revised regulations. It simply promulgated final revised regulations relying on that expanded data base.

In deciding that the Administrator had complied with the APA, the court of appeals cited its prior decision in *South Terminal Corp.* v. *Environmental Protection Agency*, 504 F.2d 646 (1st Cir. 1974). At issue in *South Terminal* were the EPA regulations for attaining the Clean Air Act's national ambient air quality standards in Boston by reducing vehicular traffic. The notice of proposed rulemaking included specific measures for achieving that goal. The notice also stated that alternatives were being considered and identified certain alternatives. Id. at 657. The final regulations adopted alternatives, including a freeze on the number of parking spaces at Logan Airport and other locations, which had not been identified in the notice of proposed rulemaking. The First Circuit held that the Administrator's notice of the proposed rules constituted sufficient notice to support his ultimate decision to adopt a different approach because the "notice left no doubt that EPA would consider all reasonable alternatives for cutting down vehicle use." *Id.* at 659. Thus, under the First Circuit's decision in *South Terminal*, a commenter which knew or should have known that the agency will consider alternatives to the initial proposal is not entitled to notice of or to comment on the alternatives finally selected no matter how much the alternative differs from the proposal.

The court of appeals in this case applied the principle developed in *South Terminal* in holding that interested persons should have anticipated that criticisms of the EPA's interim final subcategories could lead to the alternative of eliminating subcategories even though EPA never disclosed an intent to consider that alternative. The First Circuit extended the rationale of *South Terminal* by holding that interested persons are not entitled to notice of and an opportunity to comment on the new data relied upon by EPA in establishing the final regulations if the data disclosed with a proposed (or interim final) regulation reveal the general issues as to the use of data and provide sufficient information for commenters to generate additional data for submission and use by the agency.

B. The Decision Is In Conflict With Decisions of the Courts of Appeals for the Second, Fourth, and District of Columbia Circuits.

The First Circuit's decision conflicts with *National Crushed Stone Association* v. *Environmental Protection Agency*, 601 F.2d 111 (4th Cir. 1979), *Weyerhaeuser Corp.* v. *Costle*, 590 F.2d 1011 (D.C. Cir. 1978), and *United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), insofar as it holds that EPA was not required to issue notice and allow public comment on substantially revised regulations based on new data and information.[6]

In *National Crushed Stone*, the Agency had modified the interim final regulations for crushed stone and construction sand and gravel facilities by increasing the 30-day average effluent limitation for total suspended solids ("TSS") and by adding a maximum daily effluent limitation for TSS. 601 F.2d at 115. The changes were made on the basis of data collected by the Agency's contractor (Versar) on which there was no opportunity for public comment. *Id.* at 117. The Fourth Circuit held:

> The objections go on and on, but enough have been related to show that they are far from frivolous, and while EPA will undoubtedly take issue with the report of [the petitioners'] engineer, we need not, and do not, decide whether the objections raised in the engineer's report are valid. What we do decide

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[6] The First Circuit's decision also is contrary to a Ninth Circuit decision on an analogous issue. *See Marathon Oil Co.* v. *Environmental Protection Agency*, 564 F.2d 1253, 1271 (9th Cir. 1977).

> is that the mistakes in the use of the Versar data, if any mistakes there were, were shown by the report to be of possible significance in the formulation of the final regulations. . . . The fact that the petitioners, and just as importantly the public, had no opportunity to comment on the use of the Versar data prior to the promulgation of the final regulations in the face of serious questions concerning the validity of their use is reason to remand the regulations for further consideration.]*Id.* at 119 (footnote omitted).]

In direct contrast, the First Circuit held that the APA is satisfied if the notice informs the public of the general issues relating to data use and provides the framework for the affected industry to generate data for submission to EPA. Under the First Circuit's rule, no obligation is imposed on the Agency to permit public comment on its new or expanded data base.

In *Weyerhaeuser*, EPA secured new data after issuing the interim final effluent regulations and after the close of the public comment period. 590 F.2d at 1029. Using that data, it recalculated the biochemical oxygen demand (BOD) effluent limitation for acetate grade dissolving sulfate pulp mills for inclusion in the final effluent regulations which were the subject of the petitions for review. *Id.* at 1029. The court held that the Agency's procedures "improperly denied petitioners the opportunity to comment on a significant part of the Agency's decisionmaking process as required by Section 553" because the "figures variously relied upon by the Agency must be validated, if at all, by reference . . . to certain data . . . obtained by the Agency after the opportunity for public comment had lapsed . . . ." *Id.* at 1030-31 (citations omitted). The court of appeals stated that the data which "were not subject to prepromulgation public scrutiny are factual matters. As such, they are especially subject to verification through the notice

and comment process and less acceptably removed therefrom." *Id.* at 1030 n. 26.

The District of Columbia Circuit's decision in *Weyerhaeuser* follows its prior decision in *Portland Cement Association* v. *Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974). In *Portland Cement*, the court of appeals found "a critical defect in the decisionmaking process in arriving at the standard under review in the initial inability of petitioners to obtain—in timely fashion—the test results and procedures used on existing plants which formed a partial basis for the emission control level adopted" in the standard of performance for new portland cement plants. 486 F.2d at 392. The court concluded:

> It is not consonant with the purpose of a rulemaking proceeding to promulgate rules on the basis of inadequate data, or on data, that, [in] critical degree, is known only to the agency. [*Id.* at 393.]

In direct contrast, the First Circuit held that inviting comments on new data used by the Agency in establishing revised final regulations is unimportant. The First Circuit attempted to distinguish *Weyerhaeuser* on the ground that the formula used by EPA to calculate the effluent limitations in that case was not set forth or explained in the record. 598 F.2d at 646 n. 15; App. A, *infra*, 15a n. 15. However, the District of Columbia Circuit clearly held that an opportunity for public comment on the data was required by the APA and that the fact that the calculations were not reflected in the record constituted additional grounds for remand.

In *Nova Scotia Food Products*, interested persons "were not informed of the scientific data, or at least a selection of such data deemed important" by the Food and Drug Administration in establishing processing standards for fish products. 568 F.2d at 251. In holding that the notice

of proposed rulemaking was deficient under the APA for failure to disclose such scientific information, the Second Circuit found:

> Scientific research is sometimes rejected for diverse inadequacies in methodology; and statistical results are sometimes rebutted because of a lack of adequate gathering technique or of supportable extrapolation. Such is the stuff of scientific debate. *To suppress meaningful comment by failure to disclose the basic data relied upon is akin to rejecting comment altogether.* [568 F.2d at 252 (emphasis added).]

The First Circuit here recognized that the issues posed difficult scientific questions, including those related to the validity of the critical ESE data. The court knew it could not "play the role of Superchemist" to resolve those issues. 598 F.2d at 649; App. A, *infra*, 23a. Nonetheless, the court held that notice and comment were not required on fundamental scientific and technical issues relating to the new data relied upon by EPA.

C. The First Circuit Erred in Deciding that EPA Had Complied With The APA.

There is substantial agreement among the courts of appeals that regulations are not necessarily legally defective if they differ, even substantially, from the regulatory proposal published for public comment. *See, e.g., South Terminal Corp.*, 504 F.2d at 659; *International Harvester Co.* v. *Ruckelshaus*, 478 F.2d 615, 632 (D.C. Cir. 1973); *California Citizens Band Association* v. *United States*, 375 F.2d 43, 48 (9th Cir.), *cert. denied*, 389 U.S. 844 (1967). However, no other case invoking the notice-and-comment issue has concerned a change in regulations which appears comparable in magnitude to the 50 to 85 percent reduction in allowable discharges from organo-nitrogen pesticide manufacturing plants as occurred in this case. The substantiality of the modification of a regulation must be a factor to be considered in applying the APA. The First Circuit erred in failing to consider that factor.

The First Circuit construed the APA as not requiring notice for comment prior to adoption as a final regulation of an alternative that is radically different from the proposed regulation as long as the Agency indicates in the initial notice that it will consider all possible alternatives. Such an interpretation provides an agency with an unlimited opportunity to preclude public comment by the simple expedient of issuing a "comprehensive notice" that it is considering all possible alternatives to its proposal. *See South Terminal Corp.*, 504 F.2d at 659.

Most importantly, the First Circuit's decision in this case obviates the purpose and function of the notice-and-comment requirements of the APA. This Court has not had occasion to provide specific guidance on the legislative purpose of the notice-and-comment requirement.

The courts of appeals, however, have identified three important functions of Section 4. First, the notice allows interested parties an opportunity to offer informed criticism and comments. *See, e.g., Ethyl Corp.* v. *Environmental Protection Agency*, 541 F.2d 1, 48 (D.C. Cir. 1976), *cert. denied*, 426 U.S. 941 (1976); *Portland Cement Association*, 486 F.2d at 392-94. Second, giving interested persons a meaningful opportunity to comment enables the Agency promulgating the rules "to educate itself before establishing rules and procedures which have a substantial impact on those regulated". *Texaco, Inc.* v. *Federal Power Commission*, 412 F.2d 740, 744 (3d Cir. 1969). Third, the dialogue of comment and agency response to comment assists the reviewing court in deciding difficult issues. *Home Box Office, Inc.* v. *Federal Communications Commission*, 567 F.2d 9, 35-36 (D.C. Cir. 1977); *see Weyerhaeuser Corp.*, 590 F.2d at 1028;

cf. Marathon Oil, 564 F.2d at 1271 n. 54. ("[C]omment is often an invaluable source of information to a reviewing court attempting to evaluate complex statistical and technological decisions.")

The decision of the First Circuit in this case is not consistent with those objectives. The First Circuit perceived the principle role of industry member comment as narrowly confined to providing the Agency with additional information and data on their plants in order to provide the Agency with the broadest possible data base. The First Circuit considered it far less important, and not sufficiently important to require further notice for comment, that the industry and other interested persons comment on the data compiled by the Agency (including the validity of that data) or on the Agency's scientific and technical inferences from the data. As a result, the First Circuit's decision unnecessarily cribs the scope of the subject matter which should be subject to informed criticism and comment.

The First Circuit assumes that the Agency is not in need of and would not benefit from the education resulting from comment, favorable or critical, on the data before it and the conclusions which reasonably can be drawn from that data.

Finally, the First Circuit's decision deprives a reviewing court of a balanced and complete record upon which to assess sometimes difficult and complex issues. This latter point is demonstrated dramatically in this case by the difficulty which the First Circuit had in resolving the issues before it and by its unique and inappropriate approaches toward resolving these issues on the basis of an administrative record which had not been subject to public scrutiny and comment. *See* pages 22-27 *infra*.

D. Eli Lilly is Particularly Harmed By The First Circuit's Ruling.

The First Circuit's decision applies with particular inequity to Eli Lilly. Eli Lilly's concern was for a single pesticide, trifluralin. Upon review of the interim final effluent limitations, Eli Lilly concluded that they were reasonable as applied to the production of trifluralin at its Lafayette, Indiana plant. Eli Lilly was not in a position to comment on whether the interim final regulations were reasonable or unreasonable for the industry as a whole or as applied to the production of pesticides by other manufacturers in a diverse industry. Therefore, Eli Lilly did not file comments on the interim final regulations or a petition for review of the interim final regulations.

Although those facts specific to Eli Lilly were set forth for the First Circuit, the court of appeals did not specifically address them.[7] By necessary implication, the First Circuit held that the interim final regulations constituted sufficient notice of the final regulations to permit Eli Lilly an adequate opportunity to participate in the rulemaking for the same reasons that it concluded that those who did comment and criticize the interim final regulations had sufficient notice of the possible outcome of their comments: "The commenters cannot claim they had no notice to propose and discuss alternatives." 598 F.2d at 643; App. A, *infra*, 10a.[8] It is unreason-

[7] The court did state that "[r]egulatory targets have no guarantee that proposed effluent limits, which they are capable of meeting, will stay the same." 598 F.2d at 646; App. A, *infra*, 15a. The issue, however is not whether Eli Lilly could rest in complete assurance that the effluent limitations applicable to its plant would remain the same. Rather the issue is whether, under the procedures adopted by the Agency, Eli Lilly was accorded the opportunity to participate in the rulemaking required by the APA.

[8] Any suggestion that Eli Lilly should have recognized that the Agency might collapse the subcategories because one commenter, as the court of appeals read its remarks, saw that possibility would be unreasonable and contrary to the Third Circuit's decision in *Wagner Elec. Corp.* v. *Volpe*, 466 F.2d 1013, 1019 (3d Cir. 1972).

able to expect that Eli Lilly should have hypothesized alternative schemes which EPA might adopt to the detriment of Eli Lilly; that Eli Lilly should have submitted comments in opposition to those schemes; or that Eli Lilly should have developed alternative approaches to the interim final subcategories which would result in reasonable effluent limitations for trifluralin.

Most importantly, however, the First Circuit's decision deprived Eli Lilly of the opportunity to comment on the determination which had an adverse impact on Eli Lilly —the determination based on an expanded data base to collapse the three interim final subcategories into one subcategory and dramatically reduce the effluent limitations for trifluralin. In short, according to the court of appeals' theory, Eli Lilly was obligated to assume that the Agency would alter its course in a manner contrary to Eli Lilly's interests and to comment accordingly on interim final regulations to which it did not object. But Eli Lilly was not entitled to comment on the changes in methodology, assumptions, or data which were the basis for the final regulations which Eli Lilly did find unreasonable and objectionable.[9]

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[9] The fact that data from Eli Lilly's plant was part of the Agency's expanded data base tends to reinforce the conclusion that the First Circuit has unjustifiably narrowed the notice-and-comment requirements of the APA. Eli Lilly operates a carbon treatment system for waste water from its trifluralin process. At EPA's request, ESE sampled the waste water going to Eli Lilly's carbon treatment system and the treated effluent from the carbon treatment system in January 1977. Eli Lilly believed that carbon treatment was being considered by EPA as a basis for the second-stage regulations implementing requirements for best available technology and that the information was being collected for the purpose of preparing such proposed regulations. *See* note 1 *supra*. In announcing the interim final regulations, EPA "emphasized" that it planned to issue "in the near future" second-stage regulations which would require "substantial further reductions in pollutants discharged" by the use of "advanced technology." 41 *Fed. Reg.* at 48091. One of the advanced technologies cited was carbon adsorption. *Id.* at 48091.

[Footnote continued on page 21]

[9] [Continued]

At no time did EPA inform Eli Lilly that the ESE data would be used in the final first-stage regulations or would be cited as evidence that substantially reduced first-stage limitations were attainable because, on their face, the data indicated that Eli Lilly's discharge of pesticides is below the level permitted by the final effluent limitations.

Eli Lilly was afforded only a limited opportunity to comment on the ESE numbers and no opportunity to comment on EPA's interpretation and use of the data. The ESE data were forwarded to Eli Lilly and Eli Lilly, noting the differences between its analytical results and ESE's, suggested further dialogue on the analytical validity of the survey data. The invitation was not accepted and the matter remained unresolved when the final regulations were promulgated.

Eli Lilly argued in the court of appeals (1) that the ESE data should not have been used because of their possible analytical invalidity; (2) that data from a survey covering the first four days of a seven-day treatment cycle of a new carbon treatment system should not have been cited as representing consistent, long-term performance of the treatment system; and (3) that, because ESE's survey conducted in accordance with EPA's request, covered only treated effluent from the carbon system and did not include certain waste streams which bypassed the carbon system, the ESE data did not demonstrate that Eli Lilly could achieve the final effluent limitations. The First Circuit rejected these arguments in large part because it found the record to be ambiguous and without support for them. *Id.* at 648, 653; App. A, *infra*, 20a, 31a. Had EPA issued a further notice for public comment on the revised regulations and on the expanded data base, Eli Lilly could have provided further information on the analytical invalidity of the data and would have had its first opportunity to comment on EPA's interpretation and use of that data.

III. EVEN IF IT WERE ASSUMED THAT EPA WAS NOT REQUIRED TO ISSUE NOTICE FOR PUBLIC COMMENT ON THE REVISED REGULATIONS, THE COURT OF APPEALS' DECISION TO DEFER TO EPA'S DETERMINATIONS BASED ON AN EXPANDED DATA BASE WAS INCORRECT AND IN CONFLICT WITH THE DECISION OF ANOTHER COURT OF APPEALS AND RESULTED IN THE COURT SUBSTITUTING ITS JUDGMENT FOR THAT OF EPA.

A. The Court of Appeals Deferred to EPA on Matters Not Subject to Public Comment, and Conducted a *De Novo* Review of New Data and Information.

The First Circuit recognized that the notice-and-comment requirements are linked to the standard to be applied in reviewing the Agency's action because that requirement "supports the assumption we make with regard to EPA's substantive decisions that those decisions are in fact the product of informed, expert reasoning tested by exposure to diverse public comment." 598 F.2d at 641; App. A, *infra*, 6a. The court stated:

> We will not remand [to the Agency] so long as the Agency has explained the facts and policies on which it relied; the facts have some basis in the record; and a reasonable person could make the judgment the Agency made. [*Id.* at 652; App. A, *infra*, 28a.]

The court held, erroneously, that interested persons had an opportunity to comment on alternative subcategorization schemes that EPA might adopt. The court of appeals did not, and could not, suggest that the expanded data base upon which EPA relied and the technical and scientific inferences which it drew from those data were "tested by exposure to diverse public comment." Nonetheless, the court deferred to determinations made by EPA which were based on such untested data and inferences.

The following are illustrative of the court's deference to EPA:

Petitioners argued that, at best, EPA had data on only a few of the forty-nine pesticides covered by the regulations (*see* note 2 *supra*) and, therefore, could not reach the critical conclusion that all pesticides can be treated to the same level. Noting that EPA's expanded data base included technical literature references on the treatment of pesticides, the court deferred to EPA's judgment, stating:

> [T]he Agency is entitled to use its chemical expertise to conclude that compounds' manufacturing processes, chemical structures, and physical properties are sufficiently related so that if one is treatable the others are likely to be as well. . . . We conclude . . . that the Agency permissibly decided that the techniques are broadly applicable to facilities manufacturing the 49 pesticides discharge of which is regulated. [598 F.2d at 656; App. A, 36a-37a. (footnote and paragraphing omitted).]

The court rejected petitioners' arguments that EPA erred in inferring from the literature, particularly literature on laboratory studies, the result which could be achieved by full scale treatment systems. The court responded that it is "up to the Agency experts to decide whether relaxing the laboratory conditions would so change the result that the pesticide could not be treated by industry." *Id.* at 652 n. 27; App. A, *infra*, 29a-30a n. 27. Most astonishing, the court of appeals conceded that it could find "no mention" in the expanded data base or EPA's evaluation of that data base of ten of the forty-nine regulated pesticides, but was "*willing to assume from EPA's general language* that it reached a similar conclusion as to these ten pesticides as well." *Id.* at 656 n. 34; App. A, *infra*, 37a n. 34 (emphasis added).[10]

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[10] The court of appeals made a number of additional "assumptions" that EPA had properly applied its expertise in evaluating and using the information before it. *See id.* at 656-57 nn. 35 & 37; App. A, *infra*, 37a n. 35, 38a-39a n. 37.

Petitioners challenged the validity of the data collected by EPA's contractor, ESE. The court of appeals concluded that "[i]f ESE's work is not reliable, then the final limitations cannot stand." *Id.* at 646; App. A, *infra*, 16a. The ESE data, and particularly the laboratory documents from which their validity must be assessed, were not made available for public review during the rulemaking.[11] The court of appeals found EPA's response in its brief and supplemental memorandum to be an inadequate response to petitioners' arguments. Rather than remand the regulations, the court adopted a new and unique approach toward reviewing agency action: "We have therefore conducted our own review." *Id.* at 649; App. A, *infra*, 22a. The court conceded that its independent review was "necessarily superficial" and inconclusive:

> We cannot be sure that these references [to the ESE records] are an adequate response to criticisms levied at ESE's general control procedures. But we cannot play the role of Superchemist. Petitioners bear an extremely heavy burden if they desire to demonstrate that the results of a rulemaking procedure are infested with fatal flaws of laboratory practice. Our review, partial and facial though it is, satisfies us of the probability that EPA was justified in basing its regulations on ESE's work. [*Id.* at 649-50; App. A, *infra*, 23a-24a (footnote omitted).]

B. The First Circuit Erred in According Judicial Deference to EPA Determinations Based on Data and Information Which Had Not Been Tested By Public Comment.

The First Circuit's decision conflicts with the District of Columbia Circuit's decision in *Weyerhaeuser Corp.* v. *Costle*, 590 F.2d 1011 (1978). The First Circuit cited *Weyerhaeuser* in support of the standard of review to be applied. 598 F.2d at 647; App. A, *infra*, 18a-19a. However, the First Circuit declined, without explanation, to follow the rule in *Weyerhaeuser* that an agency determination is not entitled to a presumption of rationality when the data upon which that determination is based have not been subject to public scrutiny. The court in *Weyerhaeuser* stated:

> This denial of an opportunity for comment on these facts further undermines our usual assumption that notice and comment rulemaking, by virtue of its accessibility to public scrutiny, achieve rational results.
>
> 27 . . . [I]t is our place only to review actions actually and properly taken by the *Agency*. If that action is improper and if we cannot be sure that under correct procedures the Agency would have reached the same conclusion, we cannot characterize that defect as harmless. [590 F.2d at 1031 & n. 27 (original emphasis).]

The District of Columbia Circuit's decision in *Weyerhaeuser* is analogous to this Court's decision in *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971). If the reviewing court determined that the explanation accompanying the initial agency decision was deficient, this Court suggested that the reviewing court require the agency to prepare additional findings explaining the basis for its action. The Court recognized that such findings would be prepared outside the normal course of agency proceedings and cautioned that they should not be accorded the usual deference: the findings "will, to some extent, be '*post hoc* rationalizations' and thus must be reviewed critically". 401 U.S. at 421.

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[11] Indeed, a complete set of laboratory documents was not turned over to EPA or petitioners by ESE until after oral argument before the First Circuit. *Id.* at 646; App. A, *infra*, 16a.

C. The First Circuit Impermissibly Substituted Its Judgment for That of the Agency.

On a number of occasions, this Court has emphasized that a reviewing court may not substitute its judgment for the judgment of the agency whose action is under review. *Bowman Transportation, Inc.* v. *Arkansas-Best Freight Systems, Inc.*, 419 U.S. 281, 285 (1974); *Federal Trade Commission* v. *Sperry & Hutchinson Co.*, 405 U.S. 233, 249 (1972); *Citizens to Preserve Overton Park*, 401 U.S. at 416.

The First Circuit was propelled into that forbidden role by its decision to review the regulations on the basis of a record incompletely tested by exposure to public comment and often devoid of EPA response to the comments which would have been made.

The court made "assumptions" that EPA had rationally resolved issues raised by petitioners when there was no evidence in the record that EPA had even considered the issues. The court conducted an unprecedented independent review of laboratory documents which EPA did not receive until after it had promulgated the final regulations. Even then, the court failed to reach a definitive conclusion as to the validity of the critical laboratory data. Yet, it upheld EPA's use of the data on the ground that petitioners had not carried their heavy burden of persuading the court that EPA had acted impermissibly.[12]

EPA did not reach a judgment that data supported by its contractor, ESE, were reliable. The court of appeals made that judgment after a "partial and facial" review.

[12] The First Circuit's procedure contrasts with the following observation of Judge McGowan: "[T]he realities of judicial scrutiny . . . do not contemplate that the court itself will, by a laborious examination of the record, formulate in the first instance the significant issues faced by the agency and articulate the rationale of their resolution." *Automotive Parts & Accessories Ass'n.* v. *Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968).

598 F.2d at 650; App. A, *infra*, 24a. The court then upheld EPA's use of the data because the petitioners had not carried their heavy burden of persuading the court that the court's uncertain conclusion as to the reliability of the ESE data was in error.

This Court rejected judicial excursions into the administrative domain in *Federal Power Commission* v. *Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326 (1976):

> At least in the absence of substantial justification for doing otherwise, a reviewing court may not after determining that additional evidence is requisite for adequate review, proceed by dictating to the agency the methods, procedures, and time dimension of the needed inquiry and order the results *to be reported to the court without opportunity for further consideration on the basis of the new evidence by the agency.* Such a procedure clearly runs the risk of 'propel[ling] the court into the domain which Comgress has set aside exclusively for the administrative agency.' *SEC* v. *Chenery Corp.*, 332 U.S. 194, 196 (1947)." [*Id.* at 333 (emphasis added and footnote omitted); *cf. Camp* v. *Pitts*, 411 U.S. 138, 141-43 (1973).]

The First Circuit's decision amounts to nothing less than the substitution of its own uncertain judgment for that which EPA should have made after notice and opportunity for comment in accordance with the APA or upon remand by the court of appeals.

CONCLUSION

For the foregoing reasons, Eli Lilly prays that the Court grant this petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case.

Respectfully submitted,

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September 21, 1979

Appendices

APPENDIX A

Nos. 77-1042, 77-1059, 77-1085, 77-1153,
78-1417, 78-1428, 78-1454 and 78-1462.

UNITED STATES COURT 0F APPEALS,
FIRST CIRCUIT

BASF WYANDOTTE CORP. *et al.*,
Petitioners,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

E. I. DU PONT DE NEMOURS & CO. *et al.*,
Petitioners,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

MONSANTO COMPANY,
Petitioner,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

DOW CHEMICAL COMPANY,
Petitioner,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

MONSANTO COMPANY,
Petitioner,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

DOW CHEMICAL COMPANY,
Petitioner,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

E. I. DU PONT DE NEMOURS & CO. *et al.*,
Petitioners,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

ELI LILLY AND COMPANY,
Petitioner,

v.

DOUGLAS M. COSTLE, as Administrator,
Environmental Protection Agency,
Respondent.

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

Argued Jan. 3, 1979

Decided May 7, 1979

Douglas E. Kliever, Washington, D.C., with whom Robert C. Barnard, Charles F. Lettow, John S. Magney, and Cleary, Gottlieb, Steen & Hamilton, Washington, D.C., were on brief, for petitioners in Nos. 77-1042, 77-1059, 77-1085, 78-1417, 78-1454, and 78-1462.

J. D. Fleming, Jr., Atlanta, Ga., with whom D. Robert Cumming, Jr., John H. Fleming, and Sutherland, Asbill & Brennan, Atlanta, Ga., were on brief, for petitioner in Nos. 77-1153 and 78-1428.

Robert L. Ackerly, Washington, D.C., with whom Richard A. Flye, Sellers, Conner & Cuneo, Washington, D.C., and Paul M. Siskind, Boston, Mass., were on brief, for intervenor.

Paul M. Kaplow, Atty., Dept. of Justice, and Colburn T. Cherney, Atty., Environmental Protection Agency, with whom James A. Rogers, Associate Gen. Counsel, Steven Schatzow, Deputy Associate Gen. Counsel, Environmental Protection Agency, James W. Moorman, Asst. Atty. Gen., and Angus MacBeth, Washington, D.C., were on brief, for respondent.

Before COFFIN, Chief Judge, BOWNES, Circuit Judge, MAZZONE,* District Judge.

COFFIN, Chief Judge.

These consolidated petitions have been brought by eleven manufacturers of pesticides[1] against the respondent, the Administrator of the Environmental Protection Agency (EPA or Agency), seeking review of regulations governing the discharge of pollutants by the pesticide industry. 40 C.F.R. Part 455, 43 Fed. Reg. 17776 and 43 Fed. Reg. 44845 (1978). An industry organization,

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* Of the District of Massachusetts, sitting by designation.

[1] The petitioners are BASF Wyandotte Corp., Diamond Shamrock Corp., FMC Corp., Olin Corp., American Cyanamid, Union Carbide Corp., E. I. duPont de Nemours & Co., Inc., Ciba-Geigy Corp., Monsanto Co., Dow Chemical Co., and Eli Lilly and Co.

the National Agricultural Chemical Association (NACA), has intervened. The Federal Water Pollution Control Act states as a "national goal that the discharge of pollutants into the navigable waters be eliminated by 1985." 33 U.S.C. § 1251(a)(1). These regulations are promulgated in response to Congress' direction that the Administrator provide guidelines for the effluent reduction possible through implementation of the "best practicable control technology currently available". 33 U.S.C. §§ 1311(b)(1)(A) and 1314(b)(1).[2]

In 1974 the Agency hired an outside contractor, Roy F. Weston, Inc. (Weston), to analyze the industry. Weston submitted its final report in December of 1975. In early 1976 EPA hired a second contractor, Environmental Science and Engineering, Inc. (ESE), to evaluate Weston's work. ESE determined that Weston's work needed improvement and undertook its own study of the industry. In late 1976 EPA published interim final regulations that were immediately effective, but on which EPA invited public comment. 41 Fed. Reg. 48087 (1976). An interim development document and an economic analysis explaining the derivation of the interim regulations were also released.

In the months following publication of the interim regulations EPA received comments on many issues raised by the regulations. EPA also collected additional data and conducted further research. In early 1978 the final regulations were published, 43 Fed.Reg. 17776 (1978), as were a final development document and economic analysis. The final regulations differed from the interim regulations in a number of significant ways. The one principally relevant in this case is that EPA finally subdivided the industry into three subcategories: (1) Or-

[2] For a more thorough discussion of the statutory framework *see Weyerhaeuser Co.* v. *Costle*, 590 F.2d 1011, 1019-1021 (D.C. Cir. 1978), and cases cited.

ganic Pesticide Chemicals Manufacturing; (2) Metallo-Organic Pesticide Chemicals Manufacturing; and (3) Pesticide Chemicals Formulating and Packaging. In the interim regulations the organic pesticide subcategory had been further divided into three subcategories. For the second and third final subcategories the regulations permit "no discharge of process waste water pollutants into navigable waters." 40 C.F.R. §§ 455.32 and 455.42. For the first subcategory, 40 C.F.R. § 455.22 limits the pounds or kilograms of chemical oxygen demand (COD), biological oxygen demand (BOD), total suspended solids, and pesticide chemicals that a plant may discharge per thousand pounds or kilograms of pesticide produced during any one day or any 30 consecutive days. The levels set are lower than the levels set by the interims for some producers and higher for others. Also the pH level (the relative acidity or alkalinity) of the effluent must be within a set range.

After the final regulations issued, one of the petitioners filed a motion for reconsideration alleging, among other things, that analytical techniques were not available to detect many pesticides at the levels stated in the regulations. EPA reexamined the record and discovered that some measurement methods that EPA thought were available might not be reliable. Accordingly, EPA amended the regulations so that the pesticide content of process waste water would be limited for the producers of only 49 out of several hundred pesticides. 43 Fed.Reg. 44845, 44856 (1978).

The first petition for review challenged the interim final regulations. When the final regulations were published we granted permission to amend so as to include review of the finals. *BASF Wyandotte Corp.* v. *Costle*, 582 F.2d 108 (1st Cir. 1978). Subsequently the petitions for review filed in other circuits were transferred to this circuit. The consolidated petitions assert several pro-

cedural and substantive errors in the regulations and their promulgation.

I. Organic Pesticide Manufacturing

A. Administrative Procedure Act Compliance

Petitioners' first complaint is that EPA failed to comply with the requirements of the Administrative Procedure Act in that the final regulations were so different from the interim final regulations that the interims were not notice of "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). This requirement is a critical one because it supports the assumption we make with regard to EPA's substantive decisions that those decisions are in fact the product of informed, expert reasoning tested by exposure to diverse public comment. Though our review of an agency's final decision is relatively narrow, we must be strict in reviewing an agency's compliance with procedural rules. *See Weyerhaeuser Co.* v. *Costle*, 590 F.2d 1011, 1027-1028 (D.C. Cir. 1978).

In this case EPA issued interim final regulations and sought comments on them. Industry representatives, government agencies, and others submitted voluminous comments on many aspects of the interim regulations. It is clear that EPA gave careful consideration to these comments. The Agency summarized the public comment, together with the Agency responses in the prologue to the final regulations. 43 Fed. Reg. 17781-85 (1978). The Agency accepted several suggestions made in comments critical of the interim regulations. For instance, EPA deleted some parameters by which the interim regulations controlled discharges,[3] abandoned use of COD/BOD ratios

[3] The interim regulations limited the phenol and ammonia content of discharges from some pesticide production plants. 41 Fed. Reg. 48088 (1976).

to supplement raw waste load data, and tried certain statistical tests proposed by commenters. EPA further demonstrated its openness to comments by eliminating, as we have noted, pesticide discharge limits for all but 49 chemicals in response to information received after the final regulations were printed.

The procedural rules were meant to ensure meaningful public participation in agency proceedings, not to be a straitjacket for agencies. An agency's promulgation of proposed rules is not a guarantee that those rules will be changed only in the ways the targets of the rules suggest. "The requirement of submission of a proposed rule for comment does not automatically generate a new opportunity for comment merely because the rule promulgated by the agency differs from the rule it proposed, partly at least in response to submissions." *International Harvester Co.* v. *Ruckelshaus*, 155 U.S.App.D.C. 411, 428, 478 F.2d 615, 632 (1973); *Weyerhaeuser Co.* v. *Costle*, *supra*, at 1031; *American Frozen Food Institute* v. *Train*, 176 U.S.App.D.C. 105, 132, 539 F.2d 107, 134 (1976). Even substantial changes in the original plan may be made so long as they are "in character with the original scheme" and "a logical outgrowth" of the notice and comment already given. *South Terminal Corp.* v. *EPA*, 504 F.2d 646, 658, 659 (1st Cir. 1974).

The essential inquiry is whether the commenters have had a fair opportunity to present their views on the contents of the final plan.[4] We must be satisfied, in other words, that given a new opportunity to comment, com-

[4] In the words of the *Attorney General's Manual on the Administrative Procedure Act* (1947), a contemporary explanation of the Act's purposes and provisions, "the notice should be sufficiently informative to assure interested persons an opportunity to participate intelligently in the rule making process." *Id.* at 30. Even where the Agency could publish the proposed rule itself, the Manual suggests that it may choose not to, issuing instead "a more general 'description of the subjects and issues involved.'" *Id.* at 29.

menters would not have their first occasion to offer new and different criticisms which the Agency might find convincing. *Weyerhaeuser*, at 1031. Thus, where the final rules "are the result of a complex mix of controversial and uncommented upon data and calculation", remand may be in order. *Id.* Similarly, where the Agency adds a new pollution control parameter without giving notice of intention to do so or receiving comments, there must be a remand to allow public comment. *American Frozen Food Institute, supra*, 176 U.S.App.D.C. at 133, 539 F.2d at 135. The question, however, always requires careful consideration on a case-by-case basis.

The first and principal change complained of is the Agency's decision to merge the first three interim subcategories [5] into a single Organic Pesticide Chemicals Manufacturing subcategory.[6] So far as the record discloses, petitioners were not aware of this change until the final regulations were promulgated and the time for comment had expired. EPA consolidated the former subcategories because it "recognized certain ambiguities were present in its subcategorization based on chemical structure. Many pesticides contain more than one functional group . . . and do not fit the former subcategorization scheme." 43 Fed.Reg. 17777 (1978). Consequently, "and

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[5] The interim regulations included separate subcategories for manufacturers of Halogenated Organic Pesticides, Organo-Phosphorous Pesticides, and Organo-Nitrogen Pesticides.

[6] Respondent incorrectly read petitioners' procedural challenge as being limited to this change. BASF petitioners' brief clearly states other alleged deficiencies in notice:

> "EPA should have exposed to public comment its decision to limit the regulations to those pesticides for which there are reliable analytical methods, its decision to adopt a single category for all organic pesticides, its determination that all pesticides can be treated to a single level regardless of differences in treatability of particular pesticides and its assessment of the applicability and effectiveness of carbon treatment and hydrolysis."

in response to industry comments", EPA undertook further research and found that "the quantities of pollutants in the effluents of those plants with the properly operated model technologies installed were similar regardless of the organic pesticide chemicals manufactured. The Agency . . . therefore concluded that the waste waters of all organic pesticide chemicals can be treated or controlled to the levels documented. . . . Thus, the final regulations do not differentiate among halogenated organic, organo-phosphorus, or organo-nitrogen pesticide chemicals." *Id.*

The industry comments were almost unanimous in condemning the three original subcategories both for being internally inconsistent and insufficiently differentiated from the other categories.[7] Comments presented statistical tests of EPA's data, purporting to show that the subcategories were not distinguishable from each other.[8] Comments also pointed to the inclusion of very different compounds within particular subcategories. The comments made a strong case against use of the interim subcategories, and EPA decided that the criticism was persuasive. It follows that EPA had to decide on an alternative unless it was to abandon regulation of the pesticide industry. Industry's preference was clear. They wanted EPA to expand the number of subcategories. They are now aggrieved because EPA accepted their criticism of the original subcategories but chose a different solution, collapsing rather than expanding them. Petitioners suggest that EPA's response took them entirely by surprise and that EPA had somehow indicated that the only issue for comments would be whether three subcategories were enough or there should be more.

Neither suggestion is grounds for remand. It should be clear to commenters when they criticize a regulatory

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[7] *See, e.g.*, comments of Mobay Chemical Corp., App. at 1753.

[8] *Id.*, App. at 1772.

scheme that if the agency accepts those criticisms, a new scheme will be substituted. The commenters cannot claim they had no notice to propose and discuss alternatives. And in fact they did so, suggesting a number of new approaches based on different ways to subcategorize the industry. In fact, at least one commenter recognized that if the existing scheme was not defensible, one alternative would be to abandon subcategories. This commenter, also a petitioner, Monsanto, wrote:

> "It is our belief that additional partitioning of chemical groups based on the above environmental impact factors must be accomplished *if the Agency intends to pursue the subcategorization approach.*" App. at 1905. (Emphasis added.)

Clearly Monsanto realized that the Agency would have to consider alternatives and was not finally committed to subcategories. Moreover, Monsanto's response indicates that the Agency had not misled petitioners into thinking that they need only state views on the desirability of more subcategories rather than the undesirability of fewer.

Another repeated call of the industry commenters was that the subcategories should be more equitably treated because the record did not support the significantly different guideline limits assigned to the different subcategories.[9] They should have realized that these criticisms, if accepted, could be resolved, among other ways, by applying the same limits to all organic pesticides. Again, though EPA's solution was not the one for which industry argued, it was suggested by and, in part, a logical outgrowth of industry's comments. They cannot

[9] Mobay, for instance, expressed its concern that the interim limitations "for the organo-phosphorus subcategory were based on prejudiced and . . . inequitable treatment when compared to the halogenated organics and organo-compounds [sic]." App. at 1755.

now complain because they misread the regulatory waters, incorrectly anticipated how EPA would react to their criticisms, and, consequently, submitted comments that left some things unsaid.

Not only do we think that petitioners had fair notice that consolidation of subcategories was an issue to comment upon, but we cannot think how their comments would have differed fundamentally if they had known what EPA would do. Though they would have had a different proposition against which to argue, their proposed solutions would, presumably, have been the same for the same reasons. They might have responded in greater volume or more vociferously, but they have not shown us that the content of their criticisms would have been different to the point that they would have stood a better chance of convincing the Agency to use more subcategories. In short, they had a fair opportunity to present their views on how the industry ought to be subcategorized. Their real complaint is that EPA rejected those views.

For the same reasons, we do not think EPA was obligated to provide further opportunity to comment on "its decision to limit the regulations to those pesticides for which there are reliable analytical methods" or "its dedetermination that all pesticides can be treated to a single level regardless of differences in treatability of particular pesticides". To the extent the latter differs from the decision to consolidate categories, it was clearly signalled in the interim regulations. As the commenters pointed out, the interim subcategories were based on physical structure and each included chemicals of diverse treatability. The industry's comments plainly suggested that treatability ought to be taken into account.[10] Similarly, as to the former, the interim regulations applied

[10] For an example, see the comments of E. I. duPont de Nemours & Co., App. at 1915.

a limit on the discharge of total pesticides to all manufacturers of pesticides. Any manufacturer that had reason to believe its pesticides could not be detected at the guideline limit had the opportunity to ask the Agency to change its regulations as to any particular pesticide or as to all pesticides. The Agency's receptiveness to such comments is indicated by the very decision attacked, its elimination of limits as to all but 49 organic pesticides when confronted with information showing that others were not reliably detectible. There was no lack of notice as to these subjects.

The last point we must address is a different and more difficult one. One of EPA's justifications for consolidating the subcategories and for reducing the discharge limits for many pesticides was the conclusion, based in part on "additional raw waste load and treatment data, and additional pilot plant and laboratory data" that "the waste waters of all organic pesticide chemicals can be treated or controlled to the levels documented in the Agency's data base." 43 Fed.Reg. at 17777. The BASF petitioners argue that since the EPA's conclusions were premised on "new data on the applicability and effectiveness of treatment by activated carbon and by hydrolysis" EPA should have entertained a new round of comments.[11]

Certainly nothing is more important than the bottom line numbers which determine whether individual plants are or are not in compliance with the regulations. The data that an agency has used to set proposed limits obviously should be subject to public comment if possible. Indeed, as another circuit court has noted, factual matters "are especially subject to verification through the

[11] It is ironic that petitioners should be attacking EPA's use of an expanded data base since a constant theme of their substantive attack on the regulations has been that EPA did not collect enough data to support the regulations.

notice and comment process and less acceptably removed therefrom." *Weyerhaeuser*, slip op. at 1030 n. 26.

This does not mean, however, that any new numbers gathered after publication of proposed regulations must be submitted for comment. It is perfectly predictable that new data will come in during the comment period, either submitted by the public with comments or collected by the agency in a continuing effort to give the regulations a more accurate foundation. The agency should be encouraged to use such information in its final calculations without thereby risking the requirement of a new comment period. Though in this instance the new information is in the form of numbers, our inquiry is no different than where the new information takes any other form. We must decide whether using new data that reduced the effluent limits for many of the producers deprived the public of a fair opportunity to present views on the final data base. If data used and disclosed for the interim regulations presented the issues for comment, then there is no need to seek new comment even though significant quantitative differences result.

We conclude that EPA was within the law. The final regulations set the pesticide discharge limit on the basis of data from nine plants with recommended pesticide removal technology. Seven of these nine plants were mentioned in the interim development document as forming the basis for or supporting the limits set by the interim regulations.[12] These seven plants accounted for about 82 per cent of the data points used to determine the final limits. Their products, treatment systems, and raw waste load were all discussed in detail in the interim development document, as was what was known of the

[12] One of these plants, able to meet the limits without all the components of a recommended treatment system, was not explicitly relied on in developing the interim limit, but was mentioned as supporting the reasonableness of the limit set.

content of their waste water discharges. On the strength of what was disclosed in the interim development document, therefore, petitioners could have commented on the applicability of these plants' treatment systems to other plants, and on the importance of different processes, products, and volumes.

More importantly, the interim development document disclosed the method by which EPA calculated the limits. This methodology was substantially the same for the interim and final regulations. EPA afforded petitioners the chance to make the most meaningful possible contribution to the regulatory process because the petitioners could use the information to collect data at their own plants, analyze it, and submit it to EPA. Not only would such input have guaranteed that EPA would be acting on the most complete data base possible, but it would have guaranteed that the special problems faced by each petitioner would have been taken account of by EPA and contributed to the resulting limitations.[13] Petitioners knew the role that every available piece of data would play in generating the limits. EPA used all the data supplied to it.

As to these seven plants, petitioners knew all they needed to know in order to make a meaningful contribution to the regulatory process and a meaningful comment on the regulations proposed. All they did not know was what the actual raw numbers would be. While these numbers were certainly crucial in setting the limits and and of obviously great interest to the petitioners, we are not convinced that knowing them would have significantly improved petitioners' opportunity to comment. They

[13] The purpose of requiring notice is to generate responses as well as to hold agencies to adequate procedures. Where petitioners do not take advantage of chances to influence the agency we must look with less favor on those petitioners' allegations of inadequacy in the result. *See Weyerhaeuser*, at 1028 n.15.

would have had a different numerical target for their many complaints about the limits set, but that would not have greatly advanced their ability to make positive contributions to the process by criticizing from their own knowledge the treatment technologies recommended, the success they could anticipate by implementing those technologies, and the analytical and statistical methodology EPA used to turn the raw numbers into effluent limits. In short, in this case, we think it was far more important for EPA to solicit comments on how it intended to collect and use data than on the data itself.[14]

Regulatory targets have no guarantee that proposed effluent limits, which they are capable of meeting, will stay the same. The purpose of soliciting comments is to be able to make informed changes, and those interest groups preferring looser limits are not the only ones whose comments are solicited. Other governmental agencies or public environmental protection groups are free to seek whatever changes they feel desirable, and the EPA is free to adopt those suggestions if it is persuaded.

As for the two plants that did not contribute to the generation of the interim limits, the same arguments apply in part. All they added to the process were more numbers to be used in the same way as the other numbers. Their treatment technologies are not markedly different from the others and conform to EPA's fully disclosed model technology.[15] Moreover, were these two

[14] To help illustrate, we think it apparent that had EPA made a serious arithmetical error in calculating the interim regulations so that the effluent limits were higher than they should have been if correctly figured, EPA would have been privileged to make the correction between proposal and final promulgation without submitting the revision for new comment.

[15] This case differs from *Weyerhaeuser*, at 1028-1031, because the Agency's final published explanation fully accounts for the limits set. There are no undisclosed numbers or factors on which the Agency must rely to support its final limits. *See id.* at 1030. The same calculations on the same factors were used for both the interim and final regulation, although the factors' values varied.

plants omitted from considération the final limits would be more stringent since both of these plants discharge more than the allowable amount of pollutants.[16]

B. EPA's Scientific Methodology

The BASF petitioners have tenaciously attacked the methodology and data used by ESE in calculating the final effluent limitations for organic pesticides. If ESE's work is not reliable, then the final limitations cannot stand. Partly because of a belated turnover of some 2000 pages of laboratory documents—all of those used by ESE for this rulemaking proceeding—we have been faced with three rounds of briefing memoranda, dealing with targets that were both moving and increasingly particularistic. If we are not to lose our bearings in this extensive crossfire of chemical expertise, it is important for us to gain and hold a perspective both as to facts and law.

ESE was retained in 1976, after EPA became dissatisfied with the work done over the prior two years by another contractor. ESE thereafter collected data from pesticide manufacturers and did its own experimentation on samples of waste water, the manufacturers furnishing 95 per cent of the data, and ESE laboratory work accounting for 5 per cent. The methodology and resulting data used by ESE to identify and quantify organic pesticides relate to two techniques, gas chromatography (GC) and thin layer chromatography (TLC). The method attracting most of the controversy in this appeal is gas chromatography. It involves vaporizing a sample of effluent, passing it through a column filled with various materials, which impeded the flow of each compound at a characteristic rate. Results are recorded on a con-

[16] Petitioners also complain about data from new plants being used to generate the final BOD and COD limits, but this was evidently because they misidentified one of the plants. In any case, substantially the same plants supplied the data for both the interim and final regulations.

tinuous chart which shows a "peak" when each compound exits the column, thus identifying it in terms of the time it appears, and which indicates concentration by the height and area of the peak. The method is neither simplistic nor self-executing. It involves the use of several columns, the testing and calibrating of each with samples containing known quantities of known pesticides, continual checking, and constant alertness for the presence of unforeseen substances which can distort the recording on the strip chart. The method succeeds only in careful and expert hands.

The lore of gas chromatography has been recognized for some time, being the subject of a handbook compiled in 1972 by EPA's Analytical Quality Control Laboratory (and the source of ESE's practices in this rulemaking procedure), the "Analysis of Pesticide Residues . . ." in 1974 and "Analytical Procedures for Pesticides Approved by EPA per 40 C.F.R. Part 136", App. 1997-2090. These compilations dealt with means of isolating interferences (distorting effects occasioned by the presence of unidentified substances), the preparation of apparatus, calibration, reagents, solvents, standard quality control practices, the preparation of samples, extraction, clean-up, and reporting. Part of the product of ESE's work lay in the development of a new handbook, the Quality Assurance Manual, which was in revision at least through September of 1977.

The factors underlying the present controversy as to the methodology of identifying and measuring organic pesticides are threefold: the complexity of the process, the high degree of elimination of pollutants required by the regulations, and the penalties for non-compliance. 33 U.S.C. § 1319. Petitioners point with dismay to the analytical obstacles, pitfalls, and limitations which EPA

acknowledges and warns against,[17] and challenge the reliability and adequacy of both GC and TLC. They further document their dismay by criticizing ESE for lack of an articulated quality control program; criticizing specific instances of ESE's work; noting the wide discrepancies between analyses of the same samples by several manufacturers and by ESE; and challenging the inclusion of a requirement based on chemical oxygen demand (COD) as not being feasible or useful.

The considerations governing our task of review in such a case as this have been recently illumined in *Weyerhaeuser Co.* v. *Costle*, at 1025, where Judge McGowan, writing for the court, said:

> "In light of the structure and aims of the Act, and the breadth of authority delegated by it to the EPA to identify highly sophisticated control technology in an area fraught with scientific uncertainty, our review function encounters significant limitations in the substantive aspect where the given statutory standards are 'arbitrary,' 'capricious,' or 'abuse of discretion.' First, it is elementary that our function is not to weigh *de novo* the available

[17] The introductory material in "Analytical Procedures" describing the application of gas chromatography to organochlorine pesticides contains such language as: "Under favorable circumstances, Strobane, toxaphene, chlordane (tech.) and others may also be determined"; "The usefulness of the method for other specific pesticides must be demonstrated by the analyst before any attempt is made to apply it to sample analysis"; when there are "complex mixtures, the individual compounds may be difficult to distinguish . . . . Provisions incorporated in this method are intended to minimize the occurrences of such interference"; "the method offers several analytical alternatives, dependent on the analyst's assessment of the nature and extent of interferences and/or the complexity of the pesticide mixtures found"; "This method is recommended for use only by experienced pesticide analysts or under the close supervision of such qualified persons"; "It is not possible to describe procedures for overcoming all of the interferences that may be encountered in industrial effluent."

> evidence and to substitute our judgment for that of the Agency. Second, an expansive concept and exercise of the review power in the eleven Courts of Appeals charged with that function could easily impede accomplishment of the Act's ambitious pollution-ending aspiration as well as its goal of industry-by-industry uniformity. *See generally*, Currie, *Judicial Review Under Federal Pollution Laws*, 62 Iowa L.Rev. 1221, 1261-71 (1977). This problem looms larger in the substantive area of review than it does in those areas involving statutory interpretation and procedural integrity because of the technological and scientific uncertainty that EPA must overcome as best it can in making the discretionary judgments delegated to it by Congress. There are also obvious limitations upon the capacity of courts to deal meaningfully with arcane areas of knowledge of this kind."

After quoting from the court's earlier opinion in *Industrial Union Dep't* v. *Hodgson*, 162 U.S.App.D.C. 331, 338-39 n. 18, 499 F.2d 467, 474-75 n. 18 (1974) ("Where existing methodology or research in a new area of regulation is deficient, the agency necessarily enjoys a broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information."), Judge McGowan summarized the court's view of its mission:

> "In these circumstances, therefore, we will be content in carrying out our substantive review (that is, assuming the statute and the requisite procedures have been followed), first, to insist upon an explanation of the facts and policy concerns relied on by the Agency in making its decision; second, to see if those facts have some basis in the record; and finally, to decide whether those facts and those legislative considerations by themselves could lead a reasonable

person to make the judgment that the Agency has made. *See Citizens to Preserve Overton Park, Inc.* v. *Volpe, supra*, 401 U.S. [402] at 416, 91 S.Ct. 814, 28 L.Ed.2d 136; *Amoco Oil Co.* v. *EPA*, 163 U.S. App.D.C. 162, 180-181, 501 F.2d 722, 740-41 (1974); *Industrial Union Dep't* v. *Hodgson, supra*, 162 U.S. App.D.C. 331, at 339-40, 499 F.2d 467, at 475-76." *Weyerhaeuser*, at 1026.

With these precepts in mind, we consider petitioners' challenges.

The first is to the reliability and adequacy of the two basic methods endorsed by EPA, gas chromatography and thin layer chromatography. Petitioner's general attack is based, as we have noted in note 17, on the acknowledged uncertainties attending the successful use of the methods in dealing with complex mixtures. It seems to us that EPA's cautions are to be preferred by far to overclaiming or overselling. It also seems to us that action of this nature, although not without risk to manufacturers, is preferable to no action at all. We are mindful of the fact that Congress contemplated a certain amount of "technology forcing", *Weyerhaeuser*, at 1057, expecting EPA "to press sometimes beyond the most advanced technology currently being used". *Id.* at 1061. Here, there is no claim that the technology has not been developed but merely that EPA has overstated its public acceptance. If the issue were whether the American Society for Testing and Materials (ASTM) and the American Public Health Association (APHA) *had approved* GC methods *for testing all three classes* of organic pesticides for which EPA claims GC to be appropriate, EPA might lose. But it seems clear to us, from the literature, including the series of manuals and handbooks dealing with both GC and TLC going back at least to 1972, and from the fact that several EPA test methods for organic pesticides have almost completed running the gamut of

ASTM and APHA approval processes, that any a priori attack on the methods must fail.

This leads us to more specific criticisms. The most sweeping of these is petitioners' claim that ESE, so far as the record discloses, pursued no systematic and reliable quality control procedures in running its tests on samples of effluent. In its initial form the argument was that the many steps [18] prescribed in the Chemistry Division and Radiochemical Laboratory Quality Assurance Manual, which ESE itself developed, were not followed. EPA's response, that this Manual was in preparation during most of the time ESE was running its tests, seems sufficient to us.[19] Petitioners counter that whether judged by the new Manual or the 1972 Handbook, ESE's procedures were nowhere described or approved by EPA. This seems to be true. Were the project for which ESE was engaged that of applying standard technology to routine operations, we might expect to find a pre-established testing procedure. But here part of the task was to find and develop the appropriate testing technology, resulting in the new Quality Assurance Manual.

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[18] These included a complete description in final project reports of methods used, a pre-established quality assurance plan for each project, the use of quality control input sheets and instrument log books, determination of maximum times for holding samples, documentation of ways in which samples were selected, calibration of instruments, frequent preparation of "linearity curves", frequent running of standards to keep track of changes on the performance of the equipment, and routine checks through running a blank (solvent extracted from distilled water) through the column, conducting duplicate analyses of the same waste water sample, and running "spiked" samples (waste water to which known quantities of pesticides have been added).

[19] Petitioners point out that tests of one manufacturer, Olin, were not completed until after the Manual was fully revised. Their argument that failure of ESE to jettison its prior procedures and follow the newly promulgated Manual in conducting the very last tests on one plant's samples constitutes adequate basis for remand seems to us utterly unrealistic.

ESE came on the scene after a prior contractor had been found inadequate. It obviously had a mandate to produce scientifically acceptable work; EPA had demonstrated its reaction to inadequacy. Between late 1976 and the fall of 1977 ESE invested 16,500 man hours in this rulemaking process. (App. 1491) As we have noted, all of its working papers, totalling 2000 pages have been turned over to petitioners. The specific criticisms we shall later discuss are the total harvest of hindsight. Most, we think, are answered satisfactorily by EPA; some are ignored. We find ourselves, as a reviewing court, dealing with adversaries who deal with the issues on different levels. Petitioners have combed the record to select what they deem to be errors or examples of sloppy work. EPA, on the other hand, seems to have adopted a rather bland approach, selecting only what it views as important challenges, and giving them a minimum response.

The issue of ESE's quality control standards offers an example of these diverse approaches. Petitioners decry the absence of a description of methods, quality control charts, the failure to prepare a "reproducible standard curve", the failure to run an adequate number of standards, an inadequate number of spiked and "method blank" samples, and duplicate analyses insufficient in quantity and quality. Their citations to the record are few. EPA's response to this range of criticism is largely set forth in the following footnote language in its memorandum responding to petitioners' reply brief: "Complaints of inadequate numbers of standard and spiked samples are refuted by laboratory documents supplied petitioners pursuant to the Court's request at argument."

We have therefore conducted our own review. It was restricted to 238 pages of ESE documents (App. 3352-3590). It was necessarily superficial, since we are not laboratory technicians, since the function of the various

forms and entries was often not self evident, and since many of the forms were illegible, some were apparently duplicates (App. 3469, 3470; 3413, 3556) or triplicates (App. 3363, 3474, 3582), and a sizeable number were upside down. We found frequent evidence that ESE testing had involved the running of duplicates,[20] standards,[21] blanks,[22] and spiked samples.[23] Occasionally we found apparently careful step-by-step instructions for performing tests (App. 3352, 3505); notations that a test was defective and ought to be repeated (App. 3476, 3502); remarks that samples had been lost (App. 3414, 3431) or that the recording pen had jiggled on several chromatograms (App. 3412); and interpretive remarks noted in December, 1978, apparently for use of petitioners (App. 3432, 3487-3489, 3491-3492, 3495). We have also read ESE's monthly progress reports to EPA and see evidence of concern for careful procedure. (App. 1453, 1455, 1456, 1460, 1461).

We cannot be sure that these references are an adequate response to criticisms levied at ESE's general control procedures. But we cannot play the role of Superchemist.[24] Petitioners bear an extremely heavy burden

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[20] Vol. 10, App. 3353, 3356, 3363, 3382, 3426, 3439, 3460, 3469, 3470, 3473, 3484, 3485, 3490, 3493, 3494, 3498, 3499, 3501, 3515, 3516, 3518, 3520, 3521, 3523, 3565, 3566, 3567, 3582, 3590.

[21] App. 3355, 3382, 3388, 3433, 3490, 3493, 3500, 3501, 3502, 3503, 3514, 3515, 3517, 3527.

[22] App. 3520, 3522, 3523, 3448, 3450, 3454, 3476, 3493, 3494, 3498, 3500.

[23] App. 3439, 3460, 3472, 3473, 3475, 3476, 3565.

[24] Here is an example of thrust and parry between chemists where we are being asked to give the final answer.

Petitioners: ESE did not run duplicates for 4 or 5 plants relied on. (Main brief, p. 46)

EPA: It did, at all 4, citing appendix references. (Main brief, p. 56, n.64)

Petitioners: But for duplicate samples to provide quality control over extraction and clean-up techniques, the duplicate

if they desire to demonstrate that the results of a rule-making procedure are infected with fatal flaws of laboratory practice. Our review, partial and facial though it is, satisfies us of the probability that EPA was justified in basing its regulation on ESE's work.

Our feeling is strengthened by our review of some of the specific instances of alleged error in results charged by petitioners. They have pointed to the wide divergence of the analyses conducted principally by manufacturers Rhom and Haas and Eli Lilly and those performed by ESE on "split" samples of the same waste water. ESE consistently found much higher quantities of pesticide in the samples. As we have indicated above, we have not found sufficient reason to reject ESE's analytical procedures or results. And, while the methods generally used by the companies were sufficiently reliable,[25] we know nothing of the procedures actually used

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samples must be independently extracted, cleaned up, and injected into the column. (Reply brief, p. 18)

EPA: But the samples were so laden with pesticide, that they had to be preserved in chloroform; this meant that when a sample container was opened, the whole sample would have to be used immediately. Hence ESE could run only injection duplicates. (Memorandum in response to petitioners' reply brief, p. 6)

Petitioners: No. The layering that might be induced by chloroform could be avoided by mixing the sample just prior to splitting. Moreover, the need to preserve the sample arose because of ESE's excessive delay. Also, ESE's alleged method does not provide for the use of chloroform. Also, the lab notes say nothing about the need to shortcut making parallel extractions. (Memorandum in response to EPA memorandum, p. 4)

[25] As EPA noted in 43 Fed.Reg. 17776, 17781 (1978):

"The analytical procedures utilized by each manufacturer were solicited by EPA and evaluated by the Environmental Monitoring and Support Laboratory in Cincinnati. The data utilized in establishing these limitations were derived from analytical methods which, in the opinion of the Cincinnati Laboratory, 'appear capable of measuring the compound with adequate sensitivity.'"

by the companies in taking and preserving these samples. We therefore cannot say that the divergence of results indicates error on the part of ESE. Moreover, of course, rejection of the lower figures is to the ultimate advantage of the companies, increasing the allowable discharge.

Petitioners also focused on what first appeared to them as a "patent error" in ESE's calculations of the amount of waste water used in a test, amounting to more than a 55 gallon drum. But this turned out to be correct, EPA saying that the sample was so polluted that it had to be diluted 250,000 times. Petitioners noted two strip charts for sample 9010, speculating that a "shoulder" indicated interference and that a peak which ran off the paper could not be only 3.6 centimeters high. But EPA counters by saying the first peak was so pesticide-laden that it did indeed run off the paper, but that the *rerun* was indeed 3.6 centimeters high. The supposed interference denoted by the shoulder was the occasion for the technician's comment we have noted concerning the jiggling of the recorder pen. App. 3412. Other charges were that two strip charts supposedly representing duplicate analysis were not "remotely comparable"—the response being that they were successive analyses with the differences due to the large amount of pesticide present in the early extractions; that ESE improperly used higher influent numbers ascertained by a Perkin-Elmer instrument with no explanation for rejecting the lower numbers obtained by a Varian instrument—the reply being that each instrument is more effective in different ranges of numbers. Although petitioners have a retort in each such instance, we must say that EPA clearly has the better of these arguments.

There are other even more minor issues where we confess that we are not sure of the winner—whether as to a particular analysis, a standard strip chart should have been verified, whether ESE's injections were too

little in volume, whether the lack of confirmatory tests on alternate columns of different polarity was significant. As to these and other issues, EPA either did not respond or did not do so at sufficient length to be understandable. But we have said enough to indicate that residual doubt on issues of increasing minuteness is far from sufficient to cause us to interpose a different judgment than that exercised by the Agency in choosing to rely on its contractor.

Petitioners have raised one additional issue of a substantive technical nature in challenging EPA's choice of COD as a parameter. The contention is that it serves no purpose where wastes possessing large amounts of salts are to be dealt with. Diamond Shamrock's data are said to be of doubtful validity. But without such data, leaving only that developed by Monsanto's Muscatine and Anniston plants, the standard would be even more stringent. Wholly apart from absence of prejudice, EPA points to the wide use of COD in industry as a measure of long term biochemical oxygen demand and a comment from Olin that "[I]t is a mystery why the Agency feels compelled to establish a limitation on BOD when COD measurements are more feasible." C.App. 212.[26] We cannot, in the words of the court in *Weyerhaeuser*, slip op. at 23, say that "a reasonable person [could not] make the judgment that the Agency has made."

C. EPA's Determination of Best Practicable Control Technology Currently Available

Even accepting the work of ESE as accurate, petitioners argue that the results do not support EPA's conclusion that carbon adsorption and hydrolysis are effective technologies for pre-treating pesticide waste streams to remove organic pesticide chemicals. Closely

[26] References to the confidential portion of the appendix will be to "C.App.".

related to this challenge are the arguments that the numbers with which EPA calculated the final effluent limits were inaccurate, thus invalidating those limits, and that EPA could not reasonably combine all manufacturers of organic pesticides into one category required to meet the same limits. EPA's decision that by using the model technology, including either carbon adsorption or hydrolysis, all plants achieved "similar" pesticide content in their effluent led EPA to conclude "that the waste waters of all organic pesticide chemicals can be treated or controlled to the levels documented in the Agency's data base." 43 Fed. Reg. 17777 (1978).

In carbon adsorption, the organic molecules reach the surface of the carbon where they diffuse into the carbon's porous structure and bind with the carbon. The molecular structure and solubility of the pesticide influence its adsorption characteristics. Periodically the carbon becomes saturated and requires regeneration which can be accomplished by incineration. The resulting flue gases are quenched, scrubbed, and discharged to the atmosphere. The carbon can then be reused, although its adsorptive capacity will be somewhat reduced.

Hydrolysis is a chemical process in which the pesticide compounds are broken down by adding a caustic (or an acid) to the waste water setting off a reaction with the water and the organic compounds. The hydroxyl or hydrogen ions attach to some part of the pesticide chemical molecule, either displacing part of the group or breaking a bond so that two or more new compounds form. The success of hydrolysis is a function of the temperature and pH (relative acidity or alkalinity) of the solution and the properties of the chemical. Some compounds hydrolyze relatively easily compared to others. The ability of a compound to be hydrolyzed can be measured in terms of the half-life of the reaction, the time it takes at a given temperature and pH to hydrolyze half the chemical

present. The shorter the half-life, the easier it is to destroy the pesticide through hydrolysis.

The regulations do not require the use of any particular treatment technology so long as the effluent limitations are met. One of the premises of the regulations, however, is that by using either carbon adsorption or hydrolysis, together with equalization and biological treatment, any plant could meet the regulations. Petitioners argue that there is no basis for this conclusion and that, therefore, we should remand the regulations as to the organic pesticides category. They suggest that the data collected at operating facilities are unrepresentative, inaccurate, and insufficient to demonstrate that those facilities achieve the results EPA claims; that even if those facilities do achieve the results claimed there is no data to suggest other plants producing other pesticides could achieve comparable results; and that EPA's references to literature and pilot studies fail to support its conclusion.

We emphasize again that our review of agency rulemaking is very limited, especially where the Agency must overcome technological and scientific uncertainty in making its delegated discretionary decisions. *See Weyerhaeuser*, at 1025. We will not remand so long as the Agency has explained the facts and policies on which it relied; the facts have some basis in the record; and a reasonable person could make the judgment the Agency made. *Id.* at 1026. Thus, the petitioners carry an extremely heavy burden when petitioning for review in such a case as this.

EPA identified eight full-scale carbon treatment systems used to reduce pesticides and five full-scale hydrolysis systems. The Agency sought information on all these facilities. One of the plants using carbon adsorption (one of the petitioners before us) disclosed neither the operating conditions of the system nor individual analyses of

its effectiveness. Information on the remaining 12 systems is presented in great detail in section VII of the Development Document. Five of the seven carbon systems achieve removal rates in excess of 99 per cent of the influent pesticide as do two of the three hydrolysis systems for which data is available as to the pesticide content of both the influent and effluent of the treatment system. The two hydrolysis systems, for which only effluent data is available reduced the pesticide level to less than 1 mg/1 (one part per million) and to below the detection point respectively. EPA has concluded that the two substandard carbon systems and one sub-standard hydrolysis system could all achieve much better results by adjusting the operating conditions of the facilities (replacing the carbon more often or holding the waste water in the treatment system for a longer period).

Petitioners attack the use of data from the carbon systems because the systems were not designed to remove pesticides. This attack is trivial. EPA faces a severe problem in regulating the pesticide industry because a great deal is not known about treatment of pesticide waste waters and because the industry is very reticent about revealing what it does (or could) know. Given this admitted information shortage EPA must make use of the information it has, recognizing the limits of the information; EPA cannot refuse to carry out its mandate, waiting for the day when it might possess perfect information.[27] Whatever reasons industry might

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[27] By the same token, petitioners' broadbased attack on EPA's use of data in literature must be rejected out of hand. Certainly the literature data are not as valuable as operating plant data would be, but the plants have not supplied enough information, and the literature is useful for what it does say. For instance, if the literature identifies a particular pesticide as amenable to treatment by adsorption or hydrolysis under laboratory conditions, that does not guarantee the same results under industrial conditions, but neither does that mean the information should be ignored. It means that, other things being equal, the pesticides can be treated. It is

have had for installing carbon treatment systems, if those systems are effective at removing pesticides then EPA can and should make use of that information. The alternative would be to ignore the mandate of the Federal Water Pollution Control Act and allow the pesticide industry to develop treatment systems at its own pace, releasing information about those systems only for the purposes and under the conditions the industry might see fit. Congress has rejected that alternative.

The same answer applies to petitioners' claim that the data on carbon treatment systems were too sparse to support any conclusion about their effectiveness. EPA had no more than 25 observations at any given facility and as few as 4 observations at another. EPA used all the data it could accumulate. Had the industry come forward with more data there is every indication that EPA would have used it. Data on the performance of the treatment systems are entirely within the control of the industry. We will not hear industry complain that EPA used insufficient data when industry was uncooperative in supplying the missing data. It was up to EPA to decide whether the limited data base was sufficient to support the conclusions reached. We hold that deciding to base conclusions on the limited data available was a reasonable exercise of discretion given the regulatory mandate.[28]

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then up to the Agency experts to decide whether relaxing the laboratory conditions would so change the result that the pesticide could not be treated by industry. Merely attacking the literature because it is experimental is no help to petitioners' cause unless they can also show that the particular conclusions drawn from the literature are unreasonable. We have found nothing in the Act to outlaw scientific deductive reasoning.

[28] EPA took account of the limited data at some plants by using a weighted average that gave relatively less weight to facilities from which it had fewer observations in the calculations of the final effluent limitations.

Petitioners suggest that even the limited data available at three of the carbon treatment plants are unrepresentative because the data were collected too soon after replacement of the carbon columns or because some wastes bypassed the treatment system being studied. The sampling at Eli Lilly covered the first 4 days of a 7 day carbon cycle. The record does not reveal why the carbon was changed just before sampling began or whether either ESE or Lilly timed the change purposely. The data, however, covered more than half the cycle, and the record reveals that the results obtained during the ESE sampling period were, if anything, unrepresentative on the high side since they showed a higher concentration of pesticide in the treatment effluent than the company found in its own studies. C.App. 217. The sampling at Hardwicke was done early in that company's normal 30 day carbon cycle, but, as EPA noted, the carbon should be changed far more frequently and the sampling was fairly representative of what would have been a reasonable carbon cycle for the plant.

Petitioners also argue that Lilly and Olin generated waste streams containing pesticides that did not pass through the treatment systems. Their citations with regard to Lilly are unconvincing. The direct communication from Lilly says nothing about a pesticide-bearing waste stream by-passing carbon treatment. The MITRE study does not support the claim. It says that the only two waste sources containing the pesticide may be combined prior to treatment. C.App. 206. We find no indication that the "Floor drains, Cooling Waters, and Miscellaneous Waste Streams" contained any pesticide. C.App. 207.

The problem with respect to Olin is not so easily disposed of. On March 15, 1977, Olin submitted its comments on the interim final regulations. It stated that EPA's data omitted "supplementary waste streams con-

taining some process wastewaters." C.App. 213A. An attachment to these comments described the supplementary waste streams as including "among other things, spills, wash-downs, vent scrubber effluents, and surface runoff. In this wastestream, the following waste by-product streams are not included: 1. PCNB Plant Hydrochloric Acid; 2. PCNB Plant Spent Sulfuric Acid; 3. TCAN Plant Hydrochloric Acid." C.App. 213A. Finally, this letter stated as "basically an intelligent guess" that 1.3 pounds of pesticide were in the supplementary waste stream (not including "TCAN, HCL, PCNB HCL and PCNB spent nitration acid."). EPA visited Olin's plant on August 17, 1977. According to a memorandum of that visit, "[p]lant personnel were unable to provide back-up information supporting the revised waste load estimates reported to EPA in a letter from Olin dated March 15, 1977. They argeed to provide the basis of these revised waste loads upon receipt of a letter from EPA." C.App. 304. On August 18, 1977, EPA sent a letter to Olin seeking, inter alia, more information about the supplementary waste streams; confirmation that "these supplementary waste streams have not been, and are not currently being treated by activated carbon, but rather are neutralized and discharged"; and confirmation that the existing "waste byproduct streams" (the acid streams) were being reused or sold. App. 2625-26. Olin answered by letter of September 14 that it had no additional data on raw waste load (other than some flow rate data); that "[t]he supplementary waste streams associated with the PCNB Plant are currently only being neutralized"; and that "[t]he information you have outlined for the current disposition of the three by-product acid streams is correct." C.App. 352-53.

EPA's response to petitioners' argument is that "[t]he truth as acknowledged by Olin, is that there are no [unaccounted for] streams." EPA brief at 62. EPA's brief-writers misread the exchange quoted above. They

interpreted Olin's acknowledgement that the three acid by-product streams were not being discharged as meaning that no supplementary waste streams were being discharged. A clear distinction was made at all times in the exchange of correspondence between the acid "by-product waste streams" and the pesticide-bearing supplementary waste stream. The latter is clearly the one of concern, and Olin clearly stated that it was being discharged with no treatment other than neutralization.

The implication is that Olin was discharging more pounds of pesticide per thousand pounds of production than the figure EPA used in calculating the limits, and, therefore, the limits were miscalculated and should be corrected.[29] The treatment given the issue in EPA's brief leaves us uncertain how to handle it. On the one hand, we might be inclined to discount an "intelligent guess" about extra pesticide when no supportive data is forthcoming despite the Agency's follow up efforts. On the other hand, though, EPA has not explained the basis for ignoring the new information, and EPA's brief deals with it on an inaccurate basis.[30] Under these circumstances we feel compelled to remand the regulations for consideration of petitioners' claim that the Olin data should not be used in calcualting the final effluent limits. It may be that EPA can easily correct any defect, but we must put them to the task.

Similar arguments are directed against plants EPA used to illustrate hydrolysis treatment. Petitioners ob-

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[29] This confusion cannot impugn the conclusion that Olin's carbon adsorption system effectively treats the waste streams that in fact pass through it.

[30] The brief-writers compound the inaccuracy (and diminish our trust in them) by arguing that the 1.3 pound figure must be disbelieved because it disagrees with data submitted by Olin on September 14, 1977. C.App. 353. That data only concerned the influent and effluent of the carbon adsorption system. The 1.3 pound figure related to waste not passing through the system.

ject to reliance on two plants claiming that in fact neither has an hydrolysis system. In fact the record reveals that both plants hydrolyze the wastes, albeit not in separate hydrolysis basins. Kerr-McGee adds a caustic to elevate the pH above 11 and elevates the temperature to facilitate the reaction. App. 991. Monsanto's Anniston plant similarly sets off a reaction with addition of caustic to raise the pH, App. 2459, though the temperature is not raised. App. 126-27. In effect, hydrolysis and biological treatment occur simultaneously. Although there may be some problem in attributing the destruction of the pesticide to one or the other cause, both treatments are recommended, and the success of these systems is relevant to whether companies can meet the guideline limits [31] and supports the conclusion that hydrolysis is being used successfully in the industry. The same holds true for Shell's Axis plant. Though there is no influent data, the effluent data indicates that with the hydrolysis system the discharge of pesticide can be reduced below the detection point.

Petitioners argue that even the plants for which EPA has operating data are far from "similar" since, for instance, their pesticide output varies between 0.0000765 and 0.00315 kg/kkg. This is indeed a rather broad range, but it does not disturb us. The Act imposes no obligation on EPA to subdivide industries so that each point-source category contains identical producers. The development document reveals that EPA carefully thought about the

[31] Petitioners also object to use of data from Hercules to calculate the effluent limits. Hercules uses neither hydrolsis nor carbon adsorption to treat its waste water. It achieves excellent results with a physical-chemical system relying on equalization ponds, gravity separation, and neutralization. Though it does not support the proposition that hydrolysis and carbon adsorption are common industry techniques, it is evidence of the levels to which pesticides can be reduced by treatment. There is no reason to ignore these results simply because they are achieved more easily than by use of the recommended model technology.

relevant factors when it divided the pesticide industry into three categories. App. 57-61. It had tried to subdivide the organic pesticides into three subcategories, and that attempt was shown to fail. In fact, as we have noted, industry commenters demonstrated that those three subcategories were indistinguishable from each other and that that subcategorization scheme was inequitable. After further study EPA concluded that there was no reason to use subcategories at all. The advantages would be negligible since there were no clear dividing lines between groups of manufacturers, and the disadvantages, as pointed out by the industry, were significant. Under the circumstances we cannot say it was unreasonable for EPA to reject industry's advice that the fewer than 30 direct dischargers of organic pesticides be divided into more than one category. Certainly we see no congressional mandate that this industry be further subcategorized.

Having decided to use a single category, EPA had to set the limits for it. Its decision to use only data from full-scale operating systems and to ignore zero-discharge plants was well within its discretion. Thus it needed a way to express the limitation more precisely than a requirement such as that all plants "do as well as the plants we have surveyed". It needed to express the results of the survey data as a number typical of the model group—that is, an average. Averaging the effluent data from the model plants is very different from averaging apples and oranges or bananas and marshmallows. If the plants performed identically, no average would be necessary. Though the plants performed differently, even very differently, we cannot see why averaging is unacceptable. The same parameter was measured in the same way and in the same units. The set of observations thus derived made up the population of which an average was desired.

The problem, as we see it, was not whether an average could be taken, but how to derive that average.[32]

EPA chose to calculate a weighted average that gave equal influence to each observation rather than to each plant. Thus the plant with 4 observations had far less influence on the final average that the plant with 450 observations, but each observation at the two plants had exactly the same influence. We are sure there were many alternatives to this system, but we cannot say that EPA went beyond its discretion in picking this one. We agree with the Fourth Circuit that "the choice of statistical methods is a matter best left to the sound discretion of the Administrator." *FMC Corp.* v. *Train*, 539 F.2d 973, 986 (4th Cir. 1976); *American Petroleum Institute* v. *EPA*, 540 F.2d 1023, 1035 (10th Cir. 1976). The choice of any given method may mean that an alternative method would yield different results. The necessary corollary, however, is that any other system chosen would be open to the same criticism. We will not leave the Agency so vulnerable.

Even if the plants studied demonstrate that carbon or hydrolysis treatment is effective for the pesticides they produce, petitioners point out that they produce only a small minority of the 49 pesticides whose discharge is controlled. This is true, but it hardly means that the regulations must be limited to those pesticides for which EPA has collected information on operating treatment systems or even to the larger group of pesticides currently being treated by adsorption or hydroylsis.[33] There is literature data which suggests that other pesticides are amenable to treatment. See note 27, *supra*. Also, the Agency is entitled to use its chemical expertise to con-

[32] The statistical methodology used in the interim regulations was fully disclosed and was the subject of extensive comment. In response to those comments EPA revised its methodology.

[33] The industry failed to supply data on some operating systems.

clude that compounds' manufacturing processes, chemical structures, and physical properties are sufficiently related so that if one is treatable the others are likely to be as well.[34] Certainty is not required. It is enough that the EPA has considered the problem and that the petitioners have failed to convince us that the conclusion is unreasonable.[35] Petitioners have presented no evidence that any particular regulated pesticide is not amenable to treatment. Moreover, we assume that if any plant had evidence that an adequate, properly run treatment facility corresponding to EPA's recommendations could not achieve the guideline limits, the plant would have a strong case that it is "fundamentally different" and entitled to less stringent limitations. 40 C.F.R. § 455.22, 43 Fed.Reg. 17780 (1978). We conclude, with the one reservation expressed above, that the Agency has demonstrated that hydrolysis and carbon adsorption are currently used, effective pesticide treatment techniques; that the Agency permissibly decided that the techniques are broadly applicable to facilities manufacturing the 49 pesticides discharge of which is regulated; and that it was within the Agency's authority to require all manufacturers of organic, non-metallo pesticides to meet the same effluent limitations.

[34] By a combination of these sources and extensions of information, EPA explicitly reached conclusions as to all but 10 of the 49 pesticides. App. 111, 113, 118-119, 126, 128-131, 132, and 138. The ten of which we find no mention are BHC, Dichloran, Mirex, Barban, Fenuron, Fenuron TCA, Swep, Dicamba, Silvex, and Perthane. We are willing to assume from EPA's general language that it reached similar conclusions as to these ten pesticides as well.

[35] There is every indication that EPA was fully aware of the various factors that, as petitioners point out, can affect the relative amenability to treatment of different pesticides. The development document mentions them. *See, e.g.*, App. 104, 110, 120. We will not assume that the Agency failed to take account of such factors when it evaluated the possibility of extending the recommended treatment techniques to other chemicals.

D. EPA's Consideration of Cost.

The Act requires EPA's assessment of best practicable control technology currently available to "include consideration of the total cost of application of technology in relation to the effluent reduction benefits to be achieved." 33 U.S.C. § 1314(b)(1)(B). Cost, however, is not a paramount consideration. Congress "self-consciously made the legislative determination that the health and safety gains that achievement of the Act's aspirations would bring to future generations will in some cases outweigh the economic dislocation it causes to the present generation." *Weyerhaeuser*, at 1037. The obligation the Act imposes on EPA is only to perform a limited cost-benefit balancing to make sure that costs are not "wholly out of proportion" to the benefits achieved. *A Legislative History of the Water Pollution Control Act Amendments of 1972* 170 (1973) (statement of Senator Muskie); *Weyerhaeuser*, at 1045 n. 52. Thus, the balancing is a relatively subsidiary task and need not be precise.[36] *Weyerhaeuser*, at 1049. The Agency has considerable discretion to decide how to go about considering costs and benefits and need not "perform the elaborate task of calculating incremental balances" of marginal costs and benefits.[37] *Id.*

[36] We are not convinced that the duty to "include consideration of cost in relation to benefit" imposed on EPA by this clause of § 1314(b)(1)(B) is significantly different from the duty imposed by the same subsection to "take into account" certain other factors. *But see Weyerhauser*, at 1045-1046. We see no more reason for us to substitute our judgment for the EPA's concerning costs and benefits, assuming that the Agency has "informed itself as to their magnitude, and reached its own express and considered [opinion]", *see id.*, than concerning the other enumerated factors.

[37] We agree with the *Weyerhaeuser* court that "when an incremental analysis has been performed by industry and submitted to EPA, it is worthy of scrutiny by the Agency." At 1048. duPont's study, indicating rapidly increasing costs for removal of incremental amounts of pollutants, certainly was "worthy of scrutiny", and we assume that EPA did not ignore it. Largely through no fault of

We are satisfied that EPA has done an acceptable job in this case. Facing a highly diverse industry, and struggling with an admitted dearth of information (for which —not without some justification—it blames the industry), EPA sought to determine on a plant-by-plant basis the capital and operating costs each plant would incur in meeting the effluent limits. EPA found only seven direct dischargers that would incur additional costs.[38] Of these, EPA predicted five faced increased annual costs equal to only 0.2 to 2.0 per cent of revenues from pesticide chemicals and would not change employment or production. A comparable estimate could not be made for one other, and the last one would face costs of 3.6 per cent of revenues. EPA concluded that the latter two might experience reduced profitability but would continue in production. Capital costs were expected to total $9.9 million and annual costs $5.1 million for the industry. 43 Fed. Reg. 17777-78 (1978).

The Agency based these estimates on model treatment techniques assuming a variety of plant sizes and treatment difficulties. The petitioners criticize the estimates and their application to plants on a variety of grounds. Though many of the criticisms may be valid, suggesting that the estimates are not perfectly accurate, none of

duPont's, however, the study tested a carbon adsorption model very different from the one that formed the basis for EPA's cost estimates. Most notably duPont studied contact times of 22, 44, and 66 minutes whereas EPA prepared cost estimates for systems with contact times of 60, 300, 600, and 750 minutes. Generally the longer the effluent remains in contact with the carbon, the more efficient the treatment will be. We are not prepared to say that the duPont study demonstrates that incremental costs of EPA's model system were wholly out of proportion to incremental benefits, nor will we require EPA explicitly to respond to every study submitted by commenters.

[38] EPA lacked information as to two others. The Agency, in a permissible exercise of discretion, did not consider costs already incurred in complying with NPDES discharge permits. *Weyerhaeuser*, at 1049.

them convince us that EPA's evaluation of costs must be rejected. There is no way the cost analysis could be more than an estimate, especially given the reticence of the industry to supply information, and EPA needed to develop no more than a rough idea of the costs the industry would incur. On the basis of its estimates, EPA decided to promulgate these regulations. We cannot say that the Agency has failed to consider costs in relation to benefits, and we find no basis on which to overrule EPA and decide that costs are wholly out of proportion to benefits.

II. Metallo-Organic Pesticide Manufacturing

Subpart B of the regulations is "applicable to discharges resulting from the manufacture of metallo-organic active ingredients containing mercury, cadmium, arsenic, or copper." 40 C.F.R. § 455.30; 43 Fed.Reg. 17786-87 (1978).[39] The regulations forbid any discharge of process waste water pollutants to navigable waters. 40 C.F.R. § 455.32. The only challenge is from one of the three manufacturers of arsenic-based pesticides, Diamond Shamrock. Diamond Shamrock alleges that its process requires it to discharge arsenic contaminated waste water and that the record fails to support EPA's conclusion that a process with no discharge is the best practicable control technology currently available.

Diamond Shamrock has twice in the past reported that its arsenic manufacturing process had no discharge of polluted waste water. In August, 1975, it reported to EPA that its "process has a negative water balance [and is] able to utilize essentially all, including rainwater from the process area, in the product." A 1972 report stated, "The arsenical unit has no discharge—its design is such

[39] " 'Metallo-organic active ingredients' means carbon containing active ingredients containing one or more metallic atoms in the structure." 40 C.F.R. § 455.31(a).

as to recycle all waters into the final product." Other reports, however, are either ambiguous or assert that Diamond Shamrock in fact discharges contaminated waste water. A 1974 study reported, "Diamond Shamrock's plant is a 'low effluent' plant, although they do discharge aqueous waste. . . . [T]he discharge of arsenic averages about 0.7-0.8 [parts per million]. . . . The total amount of arsenic discharged amounts to only about ½ lb per day."[40] In July and August, 1977, Diamond Shamrock told EPA and ESE during a meeting and during an inspection of the plant that it discharged waste water and could not meet the limit in the interim regulations. Data covering January through May of 1977 show that there is arsenic in the waste water discharged from the arsenic process to the biological treatment facility and in the discharge from the treatment facility. Flow charts describing Diamond Shamrock's production process show that waste water can be recycled, but suggest that some is not. Finally, ESE's notes of an April 26, 1976, telephone conversation between an ESE researcher and a Diamond Shamrock plant manager reveal that the plant manager admitted that arsenate production has no waste but also said the plant could not meet a limit of 0.1 parts per million.[41]

Though the record is far from clear, it indicates to us that, while Diamond Shamrock may once have been a non-discharger, at least as of the time these regulations were

[40] This study apparently formed the basis for a 1975 EPA report which, however, made a most critical error in transcription. It said, "Diamond Shamrock's plant is a 'low effluent' plant, although aqueous waste is *not* discharged. . . . [T]he discharge of arsenic averages about 0.7 to 0.8 [parts per million]. The total amount of arsenic discharged amounts to only about ½ lb/day." (Emphasis added.) The internal inconsistency is obvious.

[41] Diamond Shamrock's comments on the interim development document expressed concern about the zero discharge limit, but on the ground that there is a higher permissible level for arsenic in public water supplies.

promulgated the plant was discharging pollutants and had so advised EPA. This does not, however, end the inquiry. The fact remains that the other eight manufacturers in the metallo-organic subpart, including the two other producers of arsenic pesticides, achieve zero discharge and have not joined the petition for review,[42] and Diamond Shamrock held itself out as a non-discharger on some occasions.

Diamond Shamrock's attempts to refute EPA's evidence concerning the other plants are unpersuasive. The evidence consists of notes of phone conversations between ESE and officials at the other two arsenic plants, Vineland and Ansul. According to the notes, Vineland's chief chemist claimed all waste water is recycled to the process, and the Ansul official said, "All wastewater from the pesticide production is reused in the process; the only discharge is of non-contaminated cooling water." Though transcribed notes of phone calls are not the best possible evidence, it seems that EPA confronted stern industry resistance in its attempts to put together a more reliable data base. Industry cannot be allowed to profit from the success of its resistance to regulatory inspections. Moreover, in proceedings such as these EPA has to be able to rely on industry-supplied information, especially where dishonesty would be counter-productive for the informants.

It appears that the industry can and does produce arsenic-based pesticides without discharging polluted waste water. The statute, though, requires more; EPA must consider specific factors including "the total cost of application of technology in relation to the effluent reduction benefits to be achieved . . ., and . . . the process employed, the engineering aspects of the application of various types of control techniques, process changes, [and]

[42] One of the other arsenic producers, Ansul, has apparently ceased production. Its performance while in operation, however, is relevant in determining achievable discharge limitations.

non-water quality environmental impact . . ." 33 U.S.C. § 1314(b)(1)(B). EPA's excuse for not considering these factors is that Diamond Shamrock does not now, or at least did not in the past, discharge polluted waste water, therefore it would not have to change its process or incur any costs in meeting the regulations.[43]

The record as we construe it does not support EPA's reasoning. Diamond Shamrock is now a discharger. It will have to change something, whether in its production process or its treatment process, in order to meet the regulation. EPA must give some consideration to the cost and impact, if any, of implementing these changes and compare the cost to the reduction benefits. Until it has performed that task, EPA has not discharged its statutory responsibilities. Having failed to consider the relevant factors, EPA abused its discretion, and we must remand.

As indicated in our discussion of the required cost analysis above, the consideration may be general, and EPA has considerable discretion to determine the scope of the investigation. We also emphasize that our remand on this issue is a limited one to give EPA an opportunity to perform the statutorily mandated assignment. If EPA discovers that in fact Diamond Shamrock will not incur costs or that the benefits of the regulation are not wholly out of proportion to the costs to the industry, then we will be prepared to uphold the regulations as written.

[43] The Development Document reports as follows:

> "No cost estimates have been developed for this subcategory. The state-of-the-art at plants manufacturing metallo-organic pesticide chemicals is no discharge of process waste water pollutants. It was originally reported that all plants were no 'discharge' facilities, however, representatives of one facility (plant 19) recently indicated that there is a discharge from their manufacture of metallic-organo pesticide chemicals. This is being investigated by the Agency. The overall impact to this subcategory is expected to be minimal." App. 166.

EPA now advises us that there is not any ongoing investigation.

III. Formulators and Packagers Subcategory

Subpart C of the regulations apply to formulators and packagers of pesticides. 40 C.F.R. §§ 455.40-455.42. This segment of the industry, encompassing approximately 5300 companies, mixes technical grade pesticide chemicals with inert ingredients by dry-based, solvent-based, or liquid-based processes to produce usable commercial products. These companies are required to release "no discharge of process waste water pollutants to navigable waters". 40 C.F.R. § 455.42. EPA expects them to meet this limit by a combination of in-process controls and collection and evaporation of whatever waste water cannot be avoided. NACA, on behalf of the formulators and packagers, has intervened in these petitions for review to challenge the no discharge limitation on a number of grounds. NACA argues that EPA's data base is so inconsistent, inaccurate, and incomplete that it cannot support any conclusion and that even taking the data base at face value it does not support the conclusion EPA has reached. Further, NACA argues that EPA has failed to meet the statutory mandate to consider certain factors. 33 U.S.C § 1314(b) (1) (B).

We agree with NACA that EPA's treatment of this industry segment is not a model of administrative regulatory methodology, but, nonetheless, we find sufficient reliable data in the record to support EPA's conclusion that zero discharge is the best practicable control technology currently available for this category. We rest this conclusion on two sources of data with respect to the reliability and value of which EPA and NACA nearly agree.[44] The first of these is a telephone survey con-

[44] EPA also relied on an "Economic Analysis of Effluent Limitations Guidelines for the Pesticide Chemicals Manufacturing Point Source Category", a 1975 report entitled "Pollution Control Technology for Pesticide Formulators and Packagers" together with the telephone survey on which it was in part based, and a study of one company with 38 facilities. There is no suggestion that these studies conflict with the two we will discuss; rather, NACA argues that they are unreliable, irrelevant, or not applicable to all companies.

ducted by ESE. ESE polled, at random, a segment of the industry,[45] and compiled 47 responses.[46] Of these 47, only 3 discharge process waste water pollutants into navigable waters. Another 8 discharge waste water to privately operated treatment facilities, but such discharges would not run afoul of these regulations.[47] Thus, 94 per cent of the companies currently can comply with these regulations, and 77 per cent are not discharging any process waste water at all.

These results are confirmed by the second source, a report compiled by a contractor hired by NACA and submitted to EPA by NACA. The report's conclusions included the following:

> —"Some plants are currently operating with no discharge of process waste water. By conservative water usage and improved housekeeping practices, most plants can either eliminate or significantly reduce the volume of process waste water generated."

[45] The exact number of firms contacted is not clear from the record before us which reveals only the firms which responded to the survey. It may be that this distinction between contacts and responses accounts for the confusion reported in note 46, *infra*. NACA has not challenged, and indeed has relied upon, the random nature of this survey.

[46] EPA has reported the number surveyed to be as high as 100. NACA suggests the number of relevant responses may be as low as 40. No matter how NACA shuffles the data, however, the basic conclusion on which we rely comes forward. The great majority of formulating companies do not discharge any process waste water pollutants into navigable waters.

[47] If, as NACA asserts, future regulations outlaw these indirect discharges, NACA may challenge those regulations. We cannot overturn regulations because companies able to comply with them might be unable to comply with supposed future rules.

—"The best practicable control technology currently available for most plants in the industry appears to be an evaporative system having no effluent. For those plants that cannot effect complete evaporation of their process waste water, partial evaporation in conjunction with disposal in an approved landfill appears to be the best alternative." [48]

This study contacted 105 companies, getting 91 usable responses. Of these 91, 66 discharged no waste water. Only 5 discharged directly to navigable waters, and another 20 discharged to private treatment facilities or practiced deep well injection or ocean dumping. Thus 73 per cent of the companies have no discharge at all, and 95 per cent comply with these regulations. The results are virtually identical to ESE's results. Whatever the failings of these studies, the numbers clearly show that the great majority of formulators already meet the limitations, and it follows that meeting the regulations is practicable for the industry looked at as a whole.

NACA does not seriously dispute that conclusion. Rather NACA suggests that we should not rely on the numbers at all and that the category should not be looked at as a whole. NACA attacks the methodology of the ESE survey because two different survey forms were used, those were not completely filled out, the results have been inconsistently reported, and the survey failed to generate any information on the effectiveness of any pre-discharge waste water treatment systems. Neither we nor EPA rely on this survey for anything beyond the information that was collected—the company's formulating process and whether or not it generated or discharged process waste water. That other questions were not asked or answered is for this purpose irrelevant. Similarly, that the survey

[48] NACA notes that this conclusion is tempered by the word "appears" and by the qualification that air pollution problems that may be connected with evaporation should be studied.

results have been inconsistently reported is of no matter so long as the final tabulation is accurate. NACA challenges the survey it submitted because that survey was not designed to serve the purpose for which EPA used it, was hastily done, and left many questions unanswered. Again, our use of it, like EPA's is only for the results it did collect, not for whatever it may have failed to determine.

NACA next suggests that the formulating category should have been broken into two subcategories because EPA's first contractor, Weston, so recommended and because it is "obvious . . . that formulators whose very operations involve the use of water and other liquids will generate wastewater and cannot achieve zero discharge." EPA was in no way bound to accept its contractor's suggestion. Our inquiry is only whether the solution EPA did adopt is rational and supported by the record.

The ESE survey collected information on the type of process used as well as waste generation and discharge.[49] The survey does not support NACA's assertion that plants using water-based processes inevitably must discharge process waste water. Of the 47 responding facilities, 20 produce liquid-based pesticides. Of these 20, only 2 run afoul of these regulations by discharging process waste water directly to navigable waters. An additional 8 facilities discharge waste water to private treatment facilities. Half the liquid-based formulators have no discharge at all. These numbers clearly show that even formulators using liquid-based processes can and do achieve zero discharge.

[49] For four of the companies no process is indicated. We shall assume that the one of these which did discharge waste water used a water-based process and that the other three used dry-based processes. This puts the uncertain data in the light most favorable to NACA.

Given EPA's supported finding on the basis of the survey that the industry in large part achieved zero discharge, EPA did not need to go through the further steps of designating some number of these plants "exemplary" and averaging the zero discharge reports of the exemplary plants to set a zero discharge limit for the subcategory. To be sure, it might have been well for EPA to visit some of the facilities reporting zero discharge in order to verify the reports, but at some point EPA must be able to rely on information provided by industry, and here the companies had no incentive to report discharges below actual levels, thereby inviting regulations they could not meet.

We turn now to the factors the statute mandates that EPA consider. In particular, NACA argues that EPA has failed adequately to consider "non-water quality environmental impact" and "the total cost of application of technology in relation to the effluent reduction benefits to be achieved." 33 U.S.C. § 1314(b)(1)(B).

As we have said, the cost/benefit comparison mandated by Congress is "intended to limit the application of technology only where the additional degree of effluent reduction is wholly out of proportion to the costs of achieving such marginal level of reduction for any class or category of sources." Legislative History, *supra*, at 170; *Weyerhaeuser*, at 1045 & n. 52. Congress did not intend cost to be an unwieldy barrier to attainment of pollution control goals. We have already explained the nature of our review.

EPA devoted significant effort to discovering the economic impact of these regulations on the formulating and packaging segment of the industry. Not only did EPA attempt to find out the number of companies that would have to incur new costs to comply with the regulations, but it also prepared estimates of the cost of compliance on the assumption that small, medium, and large plants

would have to build evaporation treatment systems from scratch. NACA attacks these cost estimates on two fronts. The first is that EPA failed to consider adequately or accurately the cost of hauling waste water or sludge remaining after evaporation to a landfill. EPA's estimates are only for evaporation systems, not the alternative acceptable technology of hauling all waste water to a landfill. But evaporation is the more expensive of the two alternatives.[50] Therefore, there was no reason to consider hauling separately. EPA further asserts that the cost of hauling the sludge left after evaporation is included in its assessment of annual "operating/maintenance" costs for the evaporation system.[51] Though it might have been well for EPA to provide a more detailed itemization of its cost estimates, given the limited scope of our review, we will not impose any such mandatory duty. We have no basis on which to doubt the EPA's assertion in this regard.

NACA's second attack is that EPA used unrealistic estimates of evaporation rates. EPA used the median evaporation rate for the country in developing its estimates. NACA recognizes this by saying that the figure

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[50] This is true even if NACA's figure for the cost of contract hauling is substituted for EPA's. EPA assumed hauling would cost $5 per gallon and that hauling all waste water would, therefore, cost about $4600 per year for a medium size plant, about half the $9100 annual operating cost of an evaporation system. Using the $8.50 per gallon cost suggested by NACA, the annual cost for the same plant would go up to about $7800, still significantly less than the cost of the evaporation system.

[51] Again, even if EPA used the wrong price for contract hauling, *see* note 50, *supra*, its analysis would not be significantly in error. Operating maintenance costs comprise a very small percentage of the total annual operating costs, and, we assume, hauling costs are less than all the operating costs. Even if *all* the operating costs were for hauling, the $8.50 price would increase total operating cost by only $700 for the medium plant, raising the total annual cost to about $9800, an increase of only about 8% which would in turn increase the estimated cost per gallon at the medium plant from $0.073 per gallon to $0.079 per gallon.

used "overestimates the annual evaporation rate for approximately half the nation" and "over half the pesticide formulation plants". EPA is entitled to look at costs on an industry-wide basis as opposed to plant-by-plant. To do so EPA must be able to make some assumption about the conditions facing the industry. Certainly, using an appropriately chosen average figure is a legitimate statistical technique, especially given that EPA is doing no more than developing rough estimates to help it determine whether the cost "is wholly out of proportion" to the benefit. Moreover, EPA notes that the evaporation tank volumes allotted are more than ample to accommodate the very slow build up of waste water that might accumulate where evaporation is significantly less than the national average. This build up can be hauled periodically to landfills.

Given EPA's determination that the cost of installing and operating an evaporation system would be acceptable even for a plant that starts with no system at all and that most formulators already comply with the regulations, EPA gave ample consideration to the comparison of cost with benefit. To be sure, the record contained only scanty data on the quantity of pollutants in formulators' waste water.[52] On the other hand, EPA has discovered that the cost of compliance for the industry is small. Any discharges that trigger a requirement for a company to incur new costs must bear some pollutants, or they would not be illegal. Therefore, eliminating those discharges will produce benefits. This seems to be the implicit logic of the Agency, and we find it persuasive. It is rational to conclude that the small costs to the industry are not wholly out of proportion to the benefits. We must remember that the goal of the Act is to eliminate discharges of pollutants into navigable waters, and this effluent limitation accomplishes that goal.

[52] Weston did compile some information on the basis of literature, company data, and plant visits. App. 1711.

The Agency must also "take into account . . . non-water quality environmental impact". The District of Columbia Circuit has held that this means the Agency must inform itself of the magnitude of potential problems and reach an "express and considered conclusion about their bearing". *Weyerhaeuser*, at 1045. The Agency has done so, though in a most cursory way. 43 Fed. Reg. 17776, 17780 (1978). The Agency noted that the major problem would be sludge and concentrated waste disposal. Though there is no specific finding of the magnitude of the problem and no express statement of conclusions, it is clear that EPA considered the problems and decided they were not of sufficient magnitude to prevent promulgation of these regulations. The Agency noted that it has published guidelines on solid waste disposal, 40 C.F.R. Part 241, and that it is in the process of developing regulations under the Resource Conservation and Recovery Act of 1976, 42 U.S.C. §§ 6901, *et seq.*, to regulate hazardous wastes.[53] We infer that EPA concluded that waste disposal can be accomplished at an acceptable cost to the environment. As to air pollution EPA asserts in its brief that the Resource Conservation and Recovery Act regulations will deal with air pollution associated with disposal of hazardous waste. Though no detailed study appears in the record, the record reveals that EPA was aware of the problem, did not consider it significant, and felt that, where necessary, treatment could prevent air pollution. App. 1233. "[S]ince Congress intended EPA's internal structure to

[53] We need not concern ourselves at this time with the additional economic cost, if any, to the pesticide industry of future compliance with these regulations. EPA can more properly consider such costs in proceedings concerning those regulations. Any attempt to assess the costs of compliance with unpromulgated regulations would be premature and highly speculative. We know of no law that prohibits an agency from attacking the evils within its jurisdiction in a piece-meal fashion. A contrary rule would make the regulatory process unworkable.

protect the non-water environment, the judicial function is completed when we have assured ourselves that EPA expressly considered the probable environmental impacts of its regulations." *Weyerhaeuser*, at 1053.

Finally, NACA challenges EPA's decision that plants which both manufacture and formulate pesticides must meet the limits for manufacturing plants with no credit for any discharge from the formulation process. NACA suggests that this will force combination plants to separate their waste streams because if combined the manufacturer will have to treat the waste water to levels better than those attained by BPT. As EPA points out though, most formulation processes do not generate or discharge waste water, including many at plants that also manufacture pesticides. Also, waste flows from formulation, where they exist, will be very small compared to the flow from manufacturing. As a consequence any burden on combined plants choosing to treat wastes together should be minimal. If that assumption proves wrong, of course, the plant retains the option of keeping the formulation waste separate and evaporating it or hauling it to a landfill. It seems eminently reasonable to us that if formulation plants are required to attain zero discharge, they should not be able to discharge extra pollutants simply because they happen also to manufacture pesticides.

Because of the minor problems noted above, the regulations must be remanded. We have no reason to believe that either of the reasons for this remand—the misunderstanding concerning one company's reporting of the waste content of its discharges and the Agency's failure to consider the possible costs of implementing the regulations in the metallo-organic subcategory—will pose a serious stumbling block to final approval of the regulations. Accordingly we will retain jurisdiction over these consolidated petitions for review so that we can bring a speedy

conclusion to this case once the Agency has set the record straight and made whatever corrections it deems necessary.

So ordered.[54]

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[54] We do not reach any issues raised exclusively by Mobay Chemical Corp. in Nos. 77-1081 and 78-1223. Action on those petitions is being withheld so that counsel for Mobay and EPA may pursue efforts to settle their disputes.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 77-1042

BASF WYANDOTTE CORPORATION, ET AL.,
Petitioners,

v.

DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 77-1059

E. I. DU PONT DE NEMOURS & CO., ET AL.,
Petitioners,

v.

DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 77-1081

MOBAY CHEMICAL CORPORATION,
Petitioner,

v.

DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 77-1085

MONSANTO COMPANY,
Petitioner,

v.

DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 77-1153

DOW CHEMICAL COMPANY,
Petitioner,

v.

DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 78-1223

MOBAY CHEMICAL CORPORATION,
Petitioner,
v.
DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 78-1417

MONSANTO COMPANY,
Petitioner,
v.
DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 78-1428

DOW CHEMICAL CORPORATION,
Petitioner,
v.
DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 78-1454

E. I. DU PONT DE NEMOURS AND COMPANY,
WILMINGTON, DELAWARE 19898,
Petitioner,
v.
DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

No. 78-1462

ELI LILLY AND CO.,
Petitioner,
v.
DOUGLAS M. COSTLE, Administrator,
ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Intervenor.

ORDER OF COURT

Entered May 7, 1979

While retaining the jurisdiction of this court, these causes except Case Nos. 77-1081 and 78-1223, are re-

manded to the Agency for further proceedings in accordance with the opinion filed this day;

The respondent is to report to this court the result of the further proceedings promptly; and

Action on the petitions for review in Case Nos. 77-1081 and 78-1223 is withheld pending efforts to settle the dispute.

By the Court:

/s/ Dana H. Gallup
Clerk

A True Copy
ATTEST:

/s/ Dana H. Gallup
Clerk

[Cert. cc: Messrs. Kliever, Ackerly, Cherney, Kaplow, Fleming and Dibble.]
and EPA

APPENDIX C

[6560-01]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER N—EFFLUENT GUIDELINES AND STANDARDS

[FRL 887-6]

PART 455—PESTICIDE CHEMICALS

Manufacturing Point Source Category

AGENCY: Environmental Protection Agency.
ACTION: Final rule.

SUMMARY: These regulations limit the discharge of pollutants into navigable waters from existing manufacturers of organic pesticide chemicals, manufacturers of metallo-organic pesticide chemicals and formulators and packagers of all pesticide chemicals. These regulations are issued under the Federal Water Pollution Control Act as amended. The effluent limitations set forth herein will be incorporated in National Pollutant Discharge Elimination System (NPDES) permits issued by the Federal EPA or by States with approved programs. The effect of these regulations will be to require treatment of waste waters discharged from the above types of operations in the Pesticide Chemicals Manufacturing Point Source Category.

EFFECTIVE DATE: Immediately.

FOR FURTHER INFORMATION CONTACT:

George M. Jett, Effluent Guidelines Division (WH-552), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-426-2497.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 1976 (41 FR 48088), the EPA promulgated interim final effluent limitations guidelines based on the application of the best practicable control technology currently available (BPT) for the Pesticide Chemicals Manufacturing Point Source Category (40 CFR 455). The final regulations set forth below amend the November 1, 1976, interim final regulations, and will be applicable to existing point sources in the organic pesticide chemicals manufacturing subcategory (Subpart A), the metallo-organic pesticide chemicals manufacturing subcategory (Subpart B), and the pesticide chemicals formulating and packaging subcategory (Subpart C). These regulations include changes and clarifications which reflect comments received on the earlier rulemaking as well as the gathering and evaluation of additional data by the Agency.

The Agency is not now promulgating effluent limitations based on the application of the best available technology economically achievable (BAT) or new source performance standards (NSPS) or pretreatment standards for new or existing sources. The Agency is under court order (Natural Resources Defenses Council, Inc. et. al. v. Train, 8 ERC 2120, D.D.C. 1976) to propose those regulations by June 30, 1979 and to promulgate those regulations by December 31, 1979.

Legal Authority

These regulations are promulgated pursuant to sections 301(b)(1)(A) and 304(b) of the Federal Water Pollution Control Act as amended (33 U.S.C. 1311(b)(1)(A), 1314(b); 86 Stat. 816 et seq.) (the Act). Section 301(b)(1)(A) requires the attainment by industrial point sources of effluent limitations based on the

application of the best practicable control technology currently available (BPT) by July 1, 1977. Section 304(b)(1) provides for the promulgation of guidelines for such effluent limitations and specifies the factors to be taken into account in assessing BPT in compliance with section 301(b)(1)(A).

Summary and Basis of Regulations

Effluent limitations are established in these regulations for biochemical oxygen demand (BOD5 "day"), chemical oxygen demand (COD), total suspended solids (TSS), pesticide chemicals and pH. The regulations govern discharges of process waste water pollutants by existing sources in all subcategories of the pesticide chemicals manufacturing point source category as identified in the applicability portion of the regulations. Stormwater which is segregated from process waste water is not covered by these regulations.

The best practicable control technology currently available for controlling the discharge of process waste water pollutants includes the prevention of the pesticide introduction into waste waters, removal of the pesticides chemicals in waste waters by hydrolysis systems or sorption onto materials such as activated carbon, flow equalization and biological treatment for the organic pesticide chemicals manufacturing subcategory (Subpart A); recovery and recycle and conversion to insoluble materials with approved land disposal for the metallo-organic pesticide chemicals manufacturing subcategory (Subpart B); evaporation and/or approved land disposal for the pesticide chemicals formulating and packaging subcategory (Subpart C). In nearly all cases recovery and recycle will be applicable for Subpart C. Many formulating and packaging operations are dry processes or non-aqueous solvent processes and generate no process waste water.

The methods and analysis for BOD5, COD, TSS, and pH shall conform to the methods specified in "Guidelines

Establishing Test Procedures for the Analysis of Pollutants", 40 CFR Part 136 (41 FR 52780. December 1, 1976). Analytical methods for pesticide chemicals covered by these regulations can be obtained from Dr. James Lichtenburg, Chief, Organic Analysis Group, U.S. EPA, Environmental Monitoring and Support Laboratory, 26 St. Clair Street, Cincinnati, Ohio 45268.

Additional waste water pollutants that may be present at significant levels are ammonia and phenol, which either originate in feed stocks or are generated in the synthesis of intermediates which are not subject to these regulations. It is recommended that these pollutants be regulated on a case-by-case basis, since they do not appear in the waste streams of all manufacturers. Ammonia can be removed by a well-operated stripping unit to levels of less than 50 mg/l. Phenol can be removed to 1 mg/l by carbon sorption or biological treatment that has been adequately acclimated to the specific wastes. The economic effects of installing these technologies, however, has not been analyzed by the Agency.

A report entitled "Development Document for Interim Final Effluent Limitations Guidelines for the Pesticide Chemicals Manufacturing Point Source Category" was issued shortly after the interim final BPT regulations were published on November 1, 1976. A supplementary report on the possible economic effects of the regulations was also issued. Comments on both reports were solicited by the Agency.

The Agency evaluated the public comments and collected and analyzed additional data. A report entitled "Development Document for Final Effluent Limitations Guidelines for the Pesticide Chemicals Manufacturing Point Source Category" details the analyses undertaken in support of the final regulations. Another report entitled "Economic Analysis of Effluent Limitations Guide-

lines for the Pesticide Chemicals Manufacturing Point Source Category" details the economic analysis undertaken in support of these final regulations. Copies of both reports are available for inspection at the EPA Public Information Reference Unit, Room 2922 (EPA Library), Waterside Mall, 401 M Street SW., Washington, D.C. 20460, at all EPA regional offices, and at State water pollution control offices. Additional copies of both the economic and technical documents will be available through the National Technical Information Service, Springfield, Va. 22151.

The technical and economic analyses undertaken in support of these regulations are discussed further in Appendix A to this preamble. Significant changes from the interim final regulations are discussed below under the heading: "Summary of Major Changes".

Summary of Public Participation

At the time that interim final regulations were issued, public comments on the regulations were solicited. A summary of public participation in this rulemaking, the public comments, and the Agency's consideration and response to these comments are contained in Appendix B to this preamble.

Summary of Major Changes

As a result of the comments and evaluation from additional data, a number of changes have been made from the interim final regulations.

One major change is the consolidation of the halogenated organic, organo-phosphorus, and organo-nitrogen subcategories into a single subcategory, designated as the organic pesticide chemicals manufacturing subcategory (Subpart A). On promulgating the interim final regulations, the Agency recognized certain ambiguities were

present in its subcategorization based on chemical structure. Many pesticides contain more than one functional group, such as halogens, phosphorus, sulfur, nitrogen, etc., and do not fit the former subcategorization scheme. Such compounds could not be readily assigned to particular subcategories.

In order to resolve these ambiguities and in response to industry comments, the Agency thoroughly reexamined the data to determine whether there were reasons to provide different effluent limitations on the basis of chemical structure and other potential differences among plants. The Agency obtained additional raw waste load and treatability data, and additional pilot plant and laboratory data from both manufacturers and the research and development activities of the Agency. The Agency also visited and inspected all plants which installed carbon sorption treatment systems, studied hydrolysis reactions, and prepared an in depth literature review.

Review of raw waste load characteristics in the expanded data base revealed no consistent pattern between or within family groupings that would provide a basis for subcategorization. Differences in raw waste load affected the cost and often the type of treatment system found to be most effective for a specific plant. However, the quantities of pollutants in the effluents of those plants with the properly operated model technologies installed were similar regardless of the organic pesticide chemicals manufactured. The Agency has therefore concluded that the waste waters of all organic pesticide chemicals can be treated or controlled to the levels documented in the Agency's data base. Thus, the final regulations do not differentiate among halogenated organic, organo-phosphorus, or organo-nitrogen pesticide chemicals. Distinct subcategories for the manufacture of metallo-organic pesticide chemicals and formulating and packaging of pesticide chemicals are retained.

Major changes were also made in the statistical methods used to determine variability factors. Several commenters suggested that nonparametric or distribution free methods be used to dervive these factors. The variability factors express the relationship between the average discharge levels or performance of the treatment systems and the maximum allowable discharge levels. Goodness-of-fit tests failed to justify the universal use of the normal, two parameter lognormal, or three parameter lognormal distributions. Therefore, nonparametric methods were used.

The Agency used a weighted averaging method to determine the overall long term averages and variability factors. This insured that the contribution of a particular plant to the overall average is in proportion to the number of observations available from that plant. Detailed discussions of this method can be found in the Development Document.

Another major change relates to the design and costing of the pesticide treatment model (carbon sorption and hydrolysis). The interim final Development Document presented a single treatment model for both low and high flow ranges. In the final Development Document the Agency presents four treatment models, each appropriate for one of four flow ranges observed in the industrial survey. Construction and operating costs have increased because of recomputation on the basis of July 1977 dollars. The Engineering News Record Index was used as the source of cost data. Since the actual treated flows determined in the industrial survey were lower than those utilized in the interim final regulations, the overall treatment cost per plant has been reduced.

In addition, the Agency presents three flow ranges for the biological treatment model instead of the two presented in the interim final Development Document. These

three sizes are representative of the ranges observed in the industrial survey. These costs have also been adjusted to July 1977 dollars.

These changes have been included to present more realistic models and costs depicting the actual flows experienced in the industry. It is expected that each plant will do a complete treatability study on its particular waste before installing any treatment system.

Another change from the interim final regulations is the deletion of the phenol and ammonia limitations. The Agency understands that these pollutants are usually generated from the manufacture of intermediates which are not covered by these regulations. Furthermore, these pollutants are not present in the effluent of all point source dischargers. It is recommended that these pollutants be controlled on a case-by-case basis when issuing NPDES (National Pollutant Discharge Elimination System) permits. Guidance for control of these pollutants is found in the "Summary and Basis of Regulations".

Another change from the interim final regulations is the exclusion of asymmetrical triazines as well as symmetrical triazines. The inclusion of asymmetrical triazines in the interim final regulations was an oversight on the part of the Agency. The Agency intends to publish triazine effluent limitations guidelines in the future.

Another change from the November 1, 1976, regulations is the elimination of the use of COD/BOD ratios to predict effluent discharge levels. This technique was utilized, as pointed out in the interim final Development Document, because of the lack of data available from the industry. Since the publication of the interim final regulations, the Agency has collected additional data and information. In some cases, as much as an additional year's data have been collected. Three plants have started

up biological treatment systems and several other plants have supplied additional data from existing biological treatment systems. As a result, the final limitations for BOD5 and COD are based on effluent levels of BOD5 and COD actually being achieved by operating pesticide plants.

From an expanded data base the Agency has revised the effluent limitations guidelines for the organic pesticide chemicals manufacturing subcategory (Subpart A). The discharge levels for the metallo-organic pesticide chemicals manufacturing subcategory (Subpart B) and the formulating and packaging subcategory (Subpart C) are unchanged from the interim final regulations and remain promulgated as no discharge of process waste water pollutants.

Economic Analysis

Seven of the pesticide chemicals manufacturing plants that this regulation covers may need to install additional treatment equipment to achieve the effluent limitations. The incremental annual cost of compliance as a percentage of revenues from pesticide chemicals range from 0.2 percent to 2.0 percent for five plants. These costs will increase prices slightly and be partly absorbed by the companies. Employment and production are not expected to change due to the relatively low level of the costs.

One other plant is expected to have annual treatment costs of 3.6 percent of their annual pesticide chemicals revenues. An accurate estimate of sales revenues cannot be made for the seventh plant. This is a very small plant dedicated almost solely to the production of pesticide chemicals. This plant had temporarily ceased production of organic pesticides in May 1977, and started construction work to improve its treatment system. The additional treatment that is under construction along with the installation of a carbon sorption unit is ex-

pected to achieve the BPT limitations. While profitability of the latter two plants could be noticeably reduced, it is expected that they will continue pesticide chemicals production. The total capital expenditures for the seven manufacturers are estimated to be $9.9 million, with total annual costs of $5.1 million.

Two additional plants may also require the installation of additional treatment equipment, but the Agency has not been able to obtain adequate data from these plants to assess the economic impact of these regulations.

Agency surveys of over 100 formulators and/or packagers did not find any formulators that discharge process waste water. Therefore the Agency expects that the aggregate economic impact on this subcategory will be very small.

The Environmental Protection Agency has determined that these regulations are not a major proposal requiring preparation of an economic impact analysis as defined by Executive Orders 11821 and 11949 and OMB Circular A-107. However, the study that has been performed meets all the requirements for economic impact analyses.

Small Business Administration Loans

Section 8 of the Act authorizes the Small Business Administration, through its economic disaster loan program, to make loans to assist any small business concerns in affecting additions to or alterations in their equipment, facilities, or methods of operation so as to meet water pollution control requirements under the Act, if the plant is likely to suffer a substantial economic injury without such assistance. For further details on this Federal loan program write to EPA, Office of Analysis and Evaluation, WH-586, 401 M Street SW., Washington, D.C. 20460.

In consideration of the foregoing, 40 CFR Part 455 is hereby amended as set forth below.

Dated: April 7, 1978.

Douglas M. Costle,
Administrator.

Appendix A—Technical Summary and Basis for Regulations

(1) General methodology.

These regulations set forth the Agency's final BPT effluent limitations guidelines for the Pesticide Chemicals Manufacturing Point Source Category. The methodology used to develop these regulations is similar to that used in the development of the interim final regulations published November 1, 1976. Since that time, the Agency has gathered additional data from EPA permit applications, EPA sampling and inspections, consultant reports, industry submissions and research and development activities of the Agency. These data were evaluated to develop these regulations.

The industry was further studied to determine whether differences in raw material used, product produced, manufacturing process employed, age and size of plant, waste water constituents or other factors required development of separate limitations guidelines for different segments of the point source category. The raw waste characteristics were identified. This included an analysis of the source, flow and volume of water used in the process employed, the sources of waste and waste waters in the operation and the constituents of all waste waters. The constituents of the waste waters which should be subject to effluent limitations guidelines were identified.

The existing control and treatment technologies currently used in this industry were examined. This in-

cluded an identification of each control and treatment technology, including both in-plant and end-of-process technologies. The examination included an identification of chemical, physical, and biological characteristics of pollutants, and the effluent levels resulting from the application of each of the examined technologies. A complete and thorough statistical analysis was performed on the treated waste data. The nonwater quality environmental impacts, as well as the environmental benefits which will accrue as a result of these regulations, were also considered.

The information outlined above was then evaluated in order to determine what levels of technology constitute the best practicable control technology currently available (BPT). In identifying such technologies, various factors were considered. These included the total cost of application of the technology in relation to the effluent reduction benefits to be achieved from such application, the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, nonwater quality environmental impact (including energy requirements) and other factors.

It should be emphasized that the Agency intends to issue additional regulations for this industry. These additional regulations may include advanced technologies and in-process controls which would result in substantial further reduction in pollutants discharged by plants within this industry. Additional compounds which may be subject to future regulations include triazines, glyphosate, and zinc, manganese, tin and iron metallo-organic pesticide chemicals.

(2) Summary of conclusions with respect to the Pesticides Chemicals Manufacturing Point Source Category.

(i) Subcategorization.

There are 29 known manufacturing point source dischargers, twenty-five of which are covered by these regulations. The remaining four do not make any pesticide chemicals that are covered by these regulations. The industrial profile is presented in the Development Document.

For the purpose of establishing effluent limitations guidelines, the pesticide chemicals manufacturing point source category has been divided into three subcategories: the organic pesticide chemicals manufacturing subcategory (Subpart A,) the metallo-organic pesticide chemicals manufacturing subcategory (Subpart B), and the pesticide chemicals formulating and packaging subcategory (Subpart C). Factors such as type of product, raw waste loads, water requirements, type of manufacturing processing, and treatability of waste waters, were used to establish effluent limitations guidelines for each of the specific subcategories. In general, the most significant contributing factors were manufacturing operations and treatability of waste water based on production volume and specific waste treatment requirements. These subcategories reflect similarities and differences in the character, the volume, and the treatability of waste water streams due to manufacturing process variables.

(ii) Waste characteristics.

The significant waste water pollutants and pollutant properties resulting from pesticide chemicals manufacturing were found to be pH, total suspended solids, BOD5, COD, metals, and pesticide chemicals. Phenol and ammonia are sometimes present in significant quantities in the discharges from certain plants.

(iii) Origin of waste water pollutants.

Sources of waste water pollutants from pesticide chemicals manufacturing include aqueous wastes from reactors,

filtration systems, decanting systems, distillation, vacuum exhaust scrubbers, stripping systems, caustic scrubbers, process equipment cleanouts, production area washdowns, refining area washdowns, formulation equipment clean-up, and spill washdowns.

Effluent limitations guidelines for the pesticide chemicals manufacturing category apply to waste waters from process operations. Process waste water pollutants generally were found to be proportional to the level of production. It was therefore possible to establish effluent limitations guidelines on the basis of production.

(iv) Treatment and control technology.

Waste water treatment and control technologies have been studied for this industry to determine what is the best practicable control technology currently available.

Treatment models are described below which will attain the required effluent levels. These models do not preclude the selection of other waste water treatment alternatives which provide equivalent or better levels of treatment. The models are also used for the purpose of calculating costs to attain the limitations for those plants not currently at the level of the limitations.

BPT TECHNOLOGY LEVEL—END-OF-PIPE TREATMENT MODEL

Subcategory 1 (Subpart A) Pesticide contaminated waste waters are pretreated via gravity separation and hydrolysis or filtration and activated carbon. Incineration of concentrated waste waters is recommended. Dilute process waste water, pretreated waste water and incinerator scrubber effluent are equalized, neutralized, biologically treated, and clarified.

Subcategory 2 (Subpart B) There shall be no discharge of process waste water pollutants. Eight of the

nine producers have no discharge. Existing in-plant waste water handling procedures such as recycle are acceptable and already attain no discharge.

Subcategory 3 (Subpart C) There shall be no discharge of process waste water pollutants. Existing evaporation systems and/or approved land disposal systems can handle the minimal wastes produced by these operations, the most common practice in this subcategory is recovery and recycle of waste waters, although a large portion of the subcategory uses dry processes.

Treatment methods such as incineration, carbon sorption hydrolysis or similar processes are commonly used for the treatment of highly concentrated and difficult to treat wastes. The manufacturer is expected to determine the most economical alternatives for in-process controls and end-of-process treatment which will meet the limitations required. It should be noted that these in-process controls are commonly practiced by plants in the industry.

If thermal decomposition of waste waters is the treatment choice, provisions must be made to ensure against entry of hazardous pollutants into the atmosphere. Consideration should also be given to recovery of materials of value in the wastes.

The application of the model treatment technologies ultimately requires disposal of the pollutants removed from waste waters in the form of solid wastes and liquid concentrates. For those waste materials considered to be relatively non-hazardous and where land disposal is the choice of treatment, proper sanitary landfill technology must be followed. Some of these waste constituents are hazardous and may require special consideration in order to ensure long-term protection of the environment. All landfill sites where such hazardous wastes are disposed

should be selected so as to prevent migration of contaminants to ground or surface waters. In cases where geologic conditions may not reasonably assure this, adequate mechanical precautions (i.e., impervious liners) should be taken to ensure long-term protection of the environment from hazardous materials.

Information received during this investigation indicates that greater than 90 percent of certain organic pesticide chemicals that are reportedly treated in activated sludge plants are removed by sorption by the sludge. There are indications that some of the pesticide chemicals are not substantially biooxidized and are released back to the treatment plant in the supernatant liquid from sludge digestors. This may give rise to pesticide chemical buildup and subsequent treatment plant failure if adequate pretreatment is not in service.

In-process control is a significant pollution abatement technique in this industry. Practices such as prevention and containment of spills and leaks, segregation of waste streams, monitoring of process waste water, water conservation and reuse, waste water equalization, good housekeeping, and equipment maintenance may be necessary to eliminate or reduce the volume of process waste water requiring treatment.

(v) Statistics.

Nonparametric or distribution free statistical methods were used to determine the daily maximum and 30 day maximum variability factors. Variability factors express the relationship between the average performance of the process and the maximum allowable discharge level. The methods are distribution free in the sense that a particular distribution is not assumed for the population of daily discharge measurements. Goodness-of-fit tests failed to justify the universal use of the normal, two

parameter lognormal or three parameter lognormal distributions. Therefore, nonparametric methods were adopted.

The daily maximum variability factor for a pollutant from a particular plant is defined as the ratio of the nonparametric estimate of the 99th percentile value to the estimate of the mean. The estimates of the 99th percentile were chosen to have the probability of at least 0.50 of being greater than the actual 99th percentile and are referred to as 50 percent tolerance level estimates for the 99th percentile. An estimate selected according to this criterion from a certain number of observations, say n, is interpreted as the value below which 99 percent of the values of a future sample of size n will fall with probability of 0.50. The arithmetic average of the daily discharge measurements was used to estimate the mean of the daily discharge distribution.

The 30 day maximum variability factors were derived on the statistical theory which holds that the distribution of the mean of a sample drawn from a population distributed according to any one of a large class of different distributional forms will be approximately normally distributed. This approach is distribution free in the sense that no restrictive assumption is made regarding the form of the population distribution and is therefore consistent with the method used to derive the daily maximum variability factors. The 30 day maximum factor is defined as the estimate of the 99th percentile of the distribution of the mean of a sample of size 30 drawn from the population of daily discharge measurements divided by the average daily discharge.

The Agency used a weighted averaging method to determine overall averages of the long term values and variability factors. This insures that the contribution of a particular plant to the overall average is in proportion to the number of observations available at the plant. For

example, if one plant supplied 455 measurements for which the variability factor was 3.4 and another plant supplied 122 measurements for which the variability factor was 2.5 the average would be calculated as follows:

$$(3.4)\,(455)+(2.5)\,(122)/455+122=3.2$$

A detailed discussion of this procedure can be found in Section IX of the Development Document.

(vi) Cost estimates for control of waste water pollutants.

Capital and annual costs were computed for each subcategory on the basis of the cost per 1,000 pounds of production. Due to the complexity and degree of integration in this industry some simplifying assumptions were made in order to determine costs on a product-by-product basis. These assumptions, which result in conservative (larger than expected) cost estimates, were that:

(1) each facility in a subcategory is a discrete plant whose process waste water is treated in a single end-of-process waste treatment system,

(2) all waste waters are treated by the end-of-process treatment system regardless of the existence of less expensive and more efficient alternate disposal techniques and in-process changes which may be made, and

(3) the effluent discharged is relatively independent of the product manufactured within a subcategory.

Cost information was obtained directly from industry, from engineering firms, equipment suppliers, government sources, and available literature. Costs are based on actual industrial installations or engineering estimates for projected facilities as supplied by contributing companies. In the absence of such information, cost estimates have been developed from either plant-supplied

costs for similar waste treatment installations at plants making other similar chemicals or general cost estimates for treatment technology. The cost for each plant not currently meeting these regulations is presented in the Development Document. These costs are presented on a plant-by-plant basis.

(vii) Potential benefits to be achieved.

It is estimated that the volume of waste waters which results from operations within this category amount to 19 billion gallons each year. The point sources in this category discharge a variety of pollutants which can seriously degrade water quality and may pose serious health problems. Besides discharging materials which reduce the oxygen in receiving waters, substances such as phenols, phosphates, oil and grease, and pesticide chemicals are released.

Pesticide chemicals by definition are designed to kill or repel "target organisms". It has been found, however, that some pesticide chemicals are toxic to plants and animals other than those for which they are intended. In recent years, research and unfortunate environmental catastrophes have demonstrated that some pesticide chemicals can cause serious environmental and human health problems. Research has also disclosed that some of these pesticide chemicals degrade very slowly and have affinity for concentration in oil and fat, including animal tissues. Pesticide chemicals have been found in meat and milk sold for human consumption, as well as in mothers' milk. Tests performed with mice, rats, and other animals have shown that some pesticide chemicals can induce tumors, cause birth defects and other reproductive abnormalities, affect genetic makeup, and cause neurological and behavioral disorders.

A significant amount of pesticide chemical pollution entering the nation's waterways results from runoff from

agricultural areas. These are non-point source discharges and are not subject to these effluent limitations guidelines, which cover only the point source dischargers. While these regulations obviously will not avoid the environmental degradation which was already resulted from Endrin, Kepone, Aldrin/Dieldrin, DDT, Toxaphene, and other widely publicized pesticide chemicals pollution examples, it will limit significant point source discharges of pesticides. It may well avoid recurrences of the more infamous pollution episodes, such as the Kepone contamination in the Chesapeake Bay. It will certainly reduce the day-to-day release into the aquatic environment of man-made chemicals.

(viii) Energy requirements and nonwater quality environmental impacts.

The major nonwater quality consideration which may result from implementation of the regulations is the means of sludge and concentrated waste disposal. As the process raw waste load is reduced in volume, alternative disposal techniques become more attractive. The principles set forth in the EPA's "Guidelines for Land Disposal of Solid Wastes," 40 CFR Part 241, may be used as guidance for acceptable land disposal techniques. In addition, pursuant to the Resource Conservation and Recovery Act of 1976, Pub. L. 94-580, the Agency intends to propose rules which will regulate the transportation and the treatment, storage, and disposal of hazardous wastes. Regulations will be proposed for appropriate solid waste management. Concentrated solid wastes resulting from the manufacture of pesticide chemicals will be subject to those regulations when they become effective. In addition, the Agency has proposed regulations pursuant to the Safe Drinking Water Act, Pub. L. 93-523, governing State underground injection control programs (41 FR 36730, August 31, 1976). These regulations constitute minimum criteria for effective State programs for control of underground injection practices.

Incineration is a viable treatment for some waste streams. Associated air pollution and the need for auxiliary fuel, depending on the heating value of the waste, are considerations which must be evaluated on an individual basis.

Other nonwater quality aspects, such as noise levels, will not be perceptibly affected. Equipment associated with in-process or end-of-pipe control systems is similar to process equipment and would not add significantly to noise levels.

Energy requirements associated with treatment and control technologies in the waste water treatment model are small compared to the total energy requirements for plants in this category.

(ix) Economic and inflationary impact analysis.

The Agency has evaluated the economic effects of these regulations in terms of plant-level economic effects such as price increases, curtailments in production, and plant closures, as well as in terms of the aggregate effects of the regulations. These aggregate effects include the total additional capital requirements and total annual costs. Annual costs include operating and maintenance costs, the cost of capital, and depreciation. All dollar values are stated in July 1977 levels.

Pesticide chemicals manufacturers are primarily a part of the organic chemicals industry. Pesticide chemicals are not a homogeneous product like bulk chemicals, however, but compete among each other for a variety of crop-pest applications. There are 133 plants owned by 82 companies that produce about 1,500 registered pesticides. Formulators and packagers remix and package the chemicals before final consumption. There are approxi-

mately 5,300 formulators and packagers. The number of manufacturers and formulators that are expected to incur additional costs, is expected to be small.

Seven plants that manufacture pesticides and discharge to navigable waters may need to install additional treatment equipment to achieve these limitations. The Agency does not know whether or not two other pesticide manufacturing plants would require additional treatment, since the plants have not adequately responded to the Agency's questions. Agency surveys found none of the 100 formulators and packagers that were contacted had a discharge of process waste water. Since no formulators and packagers were uncovered that would be affected by the regulations, the aggregate economic impact is expected to be very small.

The estimated incremental annual costs as a percentage of sales revenues from pesticide chemicals range from 0.2 to 2.0 percent for five plants manufacturing pesticides. These costs will be partly passed on in the form of higher prices and partly absorbed by the corporations, but due to the small magnitude of the changes, no noticeable decreases in production or employment are expected.

The sixth plant has a somewhat higher relative cost in that the annual treatment costs are 3.6 percent of pesticide chemical revenues. This plant is likely to experience a drop in profitability if price increases cannot be easily passed on to the customers. It is not expected that this decline in profits would be so great as to cause the plant to discontinue pesticide chemical production. No plant closures are anticipated by implementation of these regulations.

For the seventh plant an accurate estimate of sales revenues cannot be made. It is a very small plant dedicated almost solely to the production of pesticide chemicals.

This plant had temporarily ceased production of organic pesticides in May 1977, and started construction work to improve its treatment system. The additional treatment that is under construction is expected to achieve these limitations. Most of the costs are expected to be absorbed by the company, and the plant will operate at the same production and employment levels as before its temporary shutdown.

The aggregate impacts, such as the demand for capital and the increases in overall costs of using pesticides, are fairly small due to the small number of plants that need to install additional treatment equipment. The total capital expenditures for the seven manufacturers is estimated to be $9.9 million. Sales of pesticide chemicals in 1975 were over $2.16 billion (manufacturers' value), so the increase in annual costs of $5.1 million is less than 0.25 percent of these sales.

Executive Order 11821 (November 27, 1974) as amended by Executive Order 11949 and implemented by OMB Circular A-107 requires that major proposals for legislation and promulgation of regulations and rules by agencies of the Executive Branch be accompanied by a statement certifying that the inflationary impact of the proposal has been evaluated. The Administrator has directed that all regulatory actions that are likely to result in (1) annualized costs of more than $100 million. (2) additional costs of production more than 5 percent of the selling price, (3) an energy consumption increase equivalent to 25,000 barrels of oil per day, or (4) an increase in demand or decrease in supply by more than 3 percent for certain essential products will require a certified economic impact analysis. The limits in these criteria have not been exceeded, but the study that has been performed meets all the requirements for an economic impact analysis.

APPENDIX B—SUMMARY OF PUBLIC PARTICIPATION

After the November 1, 1976 publication in the FEDERAL REGISTER of the interim final regulations for the pesticide chemicals manufacturing point source category, the Agency supplied the interim final Development Document to the industry, government agencies and the public sector for comments.

The following organizations responded with comments: American Cyanamid; BASF Wyandotte Corp.; Centec Consultants, Inc.; Chemagro Agriculture Division, Mobay Chemical Corp.; Ciba-Geigy Corp.; Diamond Shamrock Corp.; Dow Chemical Co.; E. I. du Ponte de Nemours & Co., Inc.; FMC Corp.; Florida Agricultural Research Institute; 3M Co.; Monsanto Co.; M & T Chemicals, Inc.; National Agricultural Chemicals Association; Olin Corp.; Ohio State University; Reichhold Chemical, Inc.; Rohm and Haas Co.; Shell Oil Co.; Stauffer Chemical Co.; Thompson-Hayward Chemical Co., Union Carbide Corp.; Velsicol Chemical Corp.; Vulcan Materials Co.; U.S. Department of Agriculture; and U.S. Department of Commerce.

The primary issues raised by commenters with respect to the interim final effluent limitations guidelines and the responses to these comments are as follows:

(1) Some commenters stated that the regulations for pesticides and phenol require control at levels less than current analytical capabilities. Others noted that EPA approved analytical methods do not exist for all pesticides and questioned whether EPA had examined the analytical techniques utilized by industry in developing the data which it submitted.

The limitations for pesticide chemicals in units of mass (or weight) per unit of production have been derived from analytical data supplied by manufacturers which are currently detecting pesticide chemicals levels at concentrations less than those required by these regulations. The analytical procedures utilized by each manufacturer were solicited by EPA and evaluated by the Environmental Monitoring and Support Laboratory in Cincinnati. The data utilized in establishing these limitations were derived from analytical methods which, in the opinion of the Cincinnati Laboratory, "appear capable of measuring the compound with adequate sensitivity." While analytical methods for all pesticide active ingredients have as yet neither been approved pursuant to section 304(g) of the Act nor published at 40 CFR Part 136, the Agency has determined that there are analytical methods with sufficient detection limits for all regulated active ingredients. Analytical methods for pesticide active ingredients may be obtained from the Environmental Monitoring and Support Laboratory. Phenol is not limited by these regulations.

The Agency recognizes that there may be instances where plants combine small volumes of pesticide chemicals wastes with large volumes of non-pesticide wastes prior to biological treatment. In these cases, analytical capabilities may be exceeded due to dilution of the pesticide wastes. Although pesticides can be detected prior to dilution, they may not be detectable in the treated effluent. If an NPDES permit requires monitoring of the treated discharge, current analytical methods may not detect pesticide chemicals and no permit violation would therefore be documented.

The Agency suggests that any plants which might encounter this situation should examine whether commingling of pesticide and non-pesticide streams serves a useful purpose. If pesticide chemicals do not experience additional removal as a result of commingling of pesticide and non-pesticide streams, these practices may not be beneficial and may even be detrimental to the treatment of the non-pesticide streams. To insure against permit

violations which may become detectable in the future, these plants may wish to monitor pesticide streams immediately after the pesticide removal treatment unit and prior to biological treatment.

(2) One commenter stated that the ammonia found in pesticide waste water was generated primarily from production of intermediates and therefore should be excluded from these regulations since only the production of active ingredient is covered.

For this reason the Agency has removed ammonia from coverage by these regulations. Raw waste levels up to 15,000 mg/l ammonia exist at certain pesticide chemicals facilities. This parameter, however, should be controlled on a case-by-case basis. Steam stripping of specific waste streams can be expected to maintain ammonia effluent levels at less than 50 mg/l.

(3) Several commenters stated that "zero discharge" for formulators/packagers (Subpart C) is unjustified for the following reasons: (a) because EPA's survey was not representative; (b) because process waste water, leaks, spills, and surface area runoff all require disposal; (c) because the model technology ultimately requires disposal of pesticide contaminated sludge (d) because it does not allow discharge into treatment facilities shared jointly with manufacturing operations; and (e) because there is no justification for "zero discharge" if the level of pesticide chemicals in the discharge is below surface water criteria for public water supplies or below levels which may remain on food products.

The Agency has determined that a substantial number of formulators/packagers currently practice no discharge of waste water pollutants via dry clean-up, recycle, reuse evaporation, suitable solid waste disposal, or because no waste water is generated. The Agency randomly selected 75 formulating and packaging facilities registered under

the Federal Insecticide, Fungicide and Rodenticide Act. Forty-four of these facilities were currently in operation and all were achieving no discharge of process waste waters. In addition, one major company with 38 formulation facilities of varying size and processes (wet, dry, and solvent) achieved no discharge of process waste waters over a 13 state area through dry processing, land disposal and evaporation. Also, a majority of facilities manufacturing and formulating reported no discharge of process waste waters from formulation operations. A majority of formulators/packagers surveyed by the National Agricultural Chemical Association achieved no discharge of process waste waters.

The no discharge of process waste waters limit for formulators/packagers applies to contaminated wastes from formulating, loading and unloading, and storage areas. Leaks and spills can be avoided by use of good housekeeping practices. Cleanup waste can be disposed of at suitable land fill operations or by evaporation. The no discharge of process waste waters requirement also applies to surface area runoff which is commingled with process waste water, but does not apply to other surface area runoff.

Disposal of pesticide contaminated sludge must be accomplished in an environmentally acceptable manner such as disposal to a specifically designated landfill engineered to prevent pollution to surface or subsurface waters.

The Agency does not intend to restrict integrated manufacturing/formulation facilities from utilizing common treatment. In such cases, however, no credit will be given for that portion of the effluent attributable to formulating or packaging.

The no discharge of process waste waters requirement is justified regardless of surface water criteria or levels which are allowed to remain on food products. The Act

requires the limitations to be technology based and the no discharge goal for pollutants is not conditioned on surface water criteria or other considerations.

(4) One commenter stated that the "zero discharge" limit is unattainable for the manufacturers of metallo-organic pesticide chemicals.

Available data demonstrate that "zero discharge" is currently being achieved at 2 arsenic-based, 3 mercury-based, and 3 copper-based metallo-organic pesticide chemical facilities. In several cases no waste water was generated; in others, a low flow was evaporated or contract hauled. Storm water runoff from a metallo-organic facility, if segregated from any process waste waters, is not covered by these regulations.

(5) Three commenters recommended a separate subcategory for pesticides with low toxicity.

The Act requires that limitations be based upon the availability of technology for the reduction or elimination of pollutants. They are not based upon the toxicity of those pollutants. Relatively low toxicity does not justify discharges in greater amounts than achievable through application of the best practicable control technology currently available.

(6) Two commenters recommended that specific limits be placed on each individual active ingredient.

There are over 600 individual pesticides of commercial importance and perhaps as many as 34,000 distinct major formulated products. Not only would the development of specific limits for each active ingredient be administratively impossible, it would also be contrary to the intent of Congress. In an industry where patent rights often restrict production to one manufacturer, that manufacturer's currently treated effluent would represent BPT and no further pollution reduction could be required. The Agency has compared effluent levels being achieved in the

manufacture of different pesticide chemicals and has documented treatment processes which are effective for many different types of pesticides.

(7) Several commenters objected to subcategorization based on chemical structure alone, stating that reactants used, reaction media, number of unit operations, degree of purification, treatability, and variability must all be considered.

The November 1, 1976 interim final regulations provided distinct subcategories for manufacturers of halogenated organic, organo-phosphorus and organo-nitrogen compounds. The above commenters and others suggested further subcategorization on the basis of the above factors and others.

The purpose of subcategorization is not to account for all differences among plants, but only to account for those differences which affect a plant's ability to achieve particular discharge levels. Since the publication of the interim final regulations, the Agency has thoroughly reexamined the pesticide manufacturing industry to determine whether there are reasons to provide different effluent limitations guidelines of the basis of alleged differences among plants. The Agency submitted additional questionnaires to all manufacturers and obtained information on additional bench scale studies, raw waste load data, and performance data. In some cases, an additional year's data were obtained. The Agency also did a thorough literature study and conducted additional pilot plant treatability studies. In addition, the Agency visited all plants with carbon sorption technology in place and conducted a survey of hydrolysis technology. The Agency compared raw waste load and treated effluent data from all types of pesticide manufacturing. Waste water characteristics were plotted versus chemical grouping in order to determine what relationship, if any, existed.

There was no apparent relationship which held uniformly. The raw waste loads among the studied plants did not appear to correlate with the former halogenated-organic, organo-phosphorus, or organo-nitrogen categories, or with any other criteria. Differences in raw waste load do affect cost and type of treatment used, but not treatability. The effluents achieved by those plants with the model treatment technologies installed and properly operated were similar despite the pesticide grouping manufactured or other factors hypothesized. some [sic] plants which manufacture halogenated organic, organo-phosphorus and organo-nitrogen pesticides use the same treatment technology. Pilot plant treatability studies have shown that certain organo-phosphorus compounds currently being removed by hydrolysis can also be removed by carbon sorption to the same effluent levels. Likewise, certain halogenated organic and organo-nitrogen compounds can be equally well treated by hydrolysis or carbon sorption. The choice of treatment thus becomes a matter of economics.

On the basis of the foregoing reexamination, the Agency has concluded that there is no basis for distinguishing between manufacturers of halogenated organic, organo-phosphorus, or organo-nitrogen pesticides. Adequate treatment of pesticide chemicals generally requires some type of pesticide removal (carbon sorption, hydrolysis, clay adsorption, lime precipitation, chemical oxidation, etc.) followed by good equalization and biological treatment. While some pesticides may be more difficult to remove than others, these differences affect the type, amount, and cost of pesticide removal, but do not affect the treatability of the pesticide chemicals to an extent that would preclude attaining the required effluent levels. Differences in cost have been taken into account and evaluated in the economic impact analysis.

The final regulations, therefore, do not differentiate among halogenated organic, organo-phosphorus, and organo-nitrogen pesticide chemicals manufacturers. Distinct subcategories for metallo-organic pesticide chemicals manufacturers and formulating and packaging are retained. This subcatgorization is more rational and equitable than that set forth in the interim final regulations, and is more easily applied to those plants which manufacture several types of pesticide products. While the commenters asserted that further subcategorization was required, adequate data have not been provided or identified which suggest subcategorization on any other basis than that embodied in these regulations.

(8) Several commenters objected to the transfer of COD/BOD ratios from one waste stream to another.

COD/BOD ratios were not utilized in any way in the development of the final guidelines. In the interim final regulations, the Agency utilized these ratios in cost calculations to supplement existing raw waste load data where plants monitor BOD or COD, but not both. The Agency has greatly expanded its data base, and the final limitations for BOD and COD are based on effluent levels of BOD and COD which are actually being achieved in plants which use and properly operate the model treatment technologies.

(9) One commenter recommended that intermediate production be included in raw waste load calculations. Two commenters recommended that raw waste loads include those portions sent to alternative disposals such as land disposal, incineration, and deep well injection. Several commenters stated that raw waste loads are not necessarily related to production.

Raw waste load is relevant only to the design and cost of treatment systems and is not the basis for the effluent limitations established by these regulations. The regula-

tions do not cover the production of intermediates, and raw waste resulting from the production of such intermediates is not included in the cost models. Plants using incineration and deep well injection techniques were not used in calculating the limitations, although the models do include the cost to incinerate concentrated or incompatible waste streams. If a plant uses a cheaper alternate disposal, the load that requires treatment would be less, resulting in a lower economic impact to meet the limitations. Accordingly, no credit is given for alternate disposal.

If process waste water from production of an active ingredient is disposed into a well, the production of that ingredient should not be included in the calculation of discharge levels for pesticide chemicals.

The Agency has concluded that in general, raw waste loads do relate to production. The Agency recognizes that in this industry, which consists primarily of batch producers, production and raw waste loads vary greatly from time to time.

(10) One commenter stated that the EPA failed to insure that raw waste load BOD values were based on acclimated seed.

The Agency has used demonstrated effluent loads, not raw waste loads in deriving its regulations. All of the data used in deriving the final regulations were supplied by the manufacturers themselves, and the Agency has assumed that steps were taken to insure adequate seed acclimation. Data have shown that proper acclimation of seed is not a particularly significant problem in well treated wastes.

(11) A number of commenters have questioned the use of COD as a regulated parameter and have suggested that it be deleted. The major reasons offered for this suggestion include: COD is not in itself a measure of

the oxygen demand which will be exerted on receiving waters, since it measures both biodegradable and refractory portions of a waste; COD is not accurately measurable in wastes with high chloride content; COD does not reflect the effect of wastes on the environment; and COD is not a measure of toxicity. One commenter urged the retention of COD as a regulated parameter, and the deletion of BOD because of alleged difficulty of measurement and unreliability of BOD test results.

The Agency has concluded that both COD and BOD are desirable parameters because they represent different features of the organic waste loads. Although there is some overlap in measurement of COD and BOD5, they are essentially complementary rather than interchangeable parameters, and both are essential to measure the over-all oxygen demand which will be exerted upon receiving waters.

The BOD5 test is essentially a bioassay procedure involving the measurement of oxygen consumed by living organisms, over a short period of time, while metabolizing the organic matter present in a waste water under conditions as similar as possible to those that occur in nature. While COD can be an indicator of long term biochemical oxygen demand, BOD5 measures the immediate impact on the receiving waters. The Agency's statistical treatment of the BOD data from existing plants adequately considered any variability due to variations inherent in the BOD analysis. In addition, most of the state, local and regional authorities have established water quality regulations utilizing BOD5 as a major parameter for the determination of oxygen demand on receiving waters.

The COD determination measures oxidation by a strong chemical oxidant and approximates the sum of the short term BOD5, the long term BOD and the refractory portion of the organic load. It is an important parameter

than [sic] can be measured within hours, in contrast to the 5 or 6 days required to obtain the BOD5 test results. Thus, toxic discharges or treatment upsets can be quickly determined and corrected. With certain wastes containing toxic substances which interfere with BOD analysis, this test may be the best method for determination of the organic load. Since the test utilizes chemical oxidation rather than a biochemical process, the result cannot always be correlated to the BOD5 of the waste water. The test result should be considered as a complementary measurement of organic matter in the waste rather than as a substitute for the BOD5 test for this category.

Based on the data supplied it appears that the parameter most frequently measured and relied upon by industry itself is COD. The broadest data base that the industry was able to supply to the Agency was COD data. The Agency has incorporated COD as a parameter because of its availability in the data submitted and because it is such a useful tool for the control of the treatment systems employed.

The recommended technologies, pesticide removal followed by biological treatment, demonstrate COD removal. The COD limitations are based on data from plants which currently employ biological treatment. Approved methods are generally available to overcome interference in the COD measurement caused by high chloride content. If it can be demonstrated that interference caused by high salinity cannot be overcome, other analytical methods may be substituted for COD.

In certain circumstances TOD (total oxygen demand) may be substituted for COD and TOC (total organic carbon) for BOD. However, an adequate correlation between these parameters should be established.

(12) One commenter questioned whether the Agency's conclusions as to the adverse effects from long term, low

level exposure to pesticides is supported by epidemiological evidence or whether it is based on extrapolation from animal studies. This commenter also suggested that the Development Document contain references to the bibliography where adverse health effects of various pollutants are noted, and recommended a discussion of the chronic effects of low levels of exposure to small amounts of pesticide chemicals and their decomposition products.

All regulated parameters display harmful effects to the environment. The Act does not require the Agency to differentiate between degrees of harm in determining the standards, but rather the standards are to be determined by the maximum degree of pollutant removal by the best practicable technology currently available. The Development Document cites sources in the bibliography when adverse health effects of various pollutants are noted.

(13) Two commenters stated that actual plants cannot achieve the percent reduction required to meet the guidelines.

Neither the interim final nor the final regulations are based on "percent reduction" but rather on effluent levels currently being achieved by plants which use the recommended technologies.

(14) Several commenters stated that carbon sorption is not a proven technology, and that its costs are too great.

Since the publication of the interim final regulations, the Agency has conducted a comprehensive review of carbon sorption technology in the pesticide manufacturing industry. There are currently at least 7 such full-scale systems in operation, treating more than 92 million gallons annually. Design criteria for five of these systems which are achieving the limitations have been utilized for estimating the costs associated with the application of

this technology. The Agency has concluded that the costs of carbon sorption treatment are not wholly disproportionate to the effluent reduction benefits.

The two carbon sorption systems which are not currently achieving the pesticide chemicals limitations are failing to do so primarily because of inadequate operation, including infrequent replacement of carbon. The Agency believes that these two systems are also capable of achieving the limitations if operated properly. Costs for pesticide removal at four different retention times at three different flow rates have been provided in the Development Document. Costs have also been developed for other methods of treatment such as hydrolysis, which may be preferable for some waste streams.

(15) One commenter stated that the feasibility of the alternative treatment systems cannot be verified because the discussion of biological treatment did not include design data, reaction kinetics, sludge growth, or production rates.

The Agency has utilized data from biological treatment systems which are currently in operation within the pesticide chemicals manufacturing industry. No attempt has been made to design systems for particular manufacturing facilities. It is expected that each manufacturer will conduct a treatability study to determine specific design criteria.

(16) One commenter stated that certain active ingredients are resistant to hydrolysis and that hydrolysis of some active ingredients may yield toxic byproducts.

The Agency recognizes that the preferred method of pesticide removal may vary depending on the pesticide to be removed. For this reason, the Agency has suggested several means of pesticide removal, including carbon sorption, hydrolysis, lime precipitation, clay sorption, resin sorption and chemical oxidation. The Agency expects that a particular manufacturing facility will choose a method of pesticide removal which is best suited for its particular situation. In no case should a pesticide removal method be selected that results in the formation of a toxic pollutant that is not adequately treated by subsequent stages of treatment.

(17) Two commenters stated that evaporation of formulation waste waters may not be feasible in some geographic locations.

The Agency recognizes that in areas of net precipitation, evaporation basins may need to be covered. The cost of a cover has been included in the Agency's cost considerations. Heating and spray recirculating waste waters are viable alternatives although these methods have not been costed by the Agency.

(18) One commenter stated that incinerators cannot cope with compounds containing chlorine due to the corrosiveness of hydrochloric acid at high temperatures.

Proper design of such incinerators can minimize the corrosion damage due to hydrochloric acid which may form. The Agency has not received any data from plants currently practicing incineration which suggest that corosion is a serious problem in this industry. To the contrary, plants in the organic chemicals industry report good operation of incinerators disposing of halogenated organic chemicals. Some recover the HCl for sale. Plants which anticipate nonpreventable corosion may elect an alternative means of treatment such as wet air oxidation.

(19) One commenter stated that highly saline waste water will result in erratic biological treatment and dilution may be required.

At least six pesticide plants currently practice dilution in order to keep salinity at suitable levels for adapted biota. At least three of these plants are currently achieving the effluent limitations for the biological parameters.

(20) One commenter requested that a discussion of reverse osmosis and ultrafiltration be included in the control technology section.

The Agency is unaware of any reverse osmosis or ultrafiltration systems currently in practice in the industry, and has not included this as a model technology for discussion in the Development Document.

(21) Several commenters stated that the costs in the interim final regulations were underestimated, and one commenter stated that total capital cost for the industry to meet the interim final limitations will be in excess of 100 million dollars.

The commenter's cost estimates are exaggerated due to faulty assumptions and changes from the interim final regulations. For instance, they included costs for removal of parameters such as ammonia, which had been regulated in the interim final but not the final regulations. In addition, they assumed that all plants must install all technologies while the Agency estimates that seven plants are expected to incur additional capital expenditures to meet these regulations. The capital cost estimate to meet this regulation is 9.9 million dollars with a total annual cost of 5.1 million dollars. The Agency's cost models are based on design criteria that will insure compliance for even the largest production, highest flow and most extensive pesticide removal required. All costs have been adjusted to July 1977, dollars using the Engineering News Record Index.

(22) One commenter stated that an economic impact based only on direct dischargers is not representative, and that indirect dischargers should be included.

The final guidelines regulate only direct dischargers, therefore the economic impact upon direct dischargers is representative. Since indirect dischargers are not affected

by this regulation, they have not been included in the impact analysis.

(23) One commenter requested that costs be expressed in terms of increases per pound of active ingredient.

For the plants for which it can be calculated, the ratio of cost per pound of active ingredient to sales price ranges from 0.2 percent to 3.6 percent to install additional treatment equipment. This is reported in a separate study entitled "Economic Analysis of Effluent Limitations Guidelines for the Pesticide Chemicals Manufacturing Point Source Category".

(24) One commenter stated that a cost/benefit ratio should be established to estimate impact on the industry.

A formal cost/benefit analysis is not required in the development of these regulations. The benefits of pollution reduction cannot be quantified precisely in monetary terms. The Agency has examined the amounts, types, and effects of the pollutants discharged by this industry and the costs of achieving the regulations. The Agency concludes that the costs associated with these regulations are not wholly disproportionate to the effluent reduction benefits.

(25) One commenter stated that costs for chemical analyses should be included in the cost models.

The Agency's cost estimates include the capital expenses of a well-equipped analytical laboratory as well as the expenses associated with monitoring the regulated parameters. No significant costs should be incurred in the development of analytical techniques for a particular active ingredient, since such techniques are available from the Environmental Monitoring and Support Laboratory.

(26) One commenter stated that the Agency failed to consider the economic impact on those formulating and packaging plants which may not have sufficient space for extensive waste treatment installations.

Agency surveys of over 100 formulators found none that directly discharged process waste waters. The number of plants that are expected to need any additional treatment is believed to very small. [sic] Evaporation ponds for the small amount of wastes require minimal land area, and recycling and/or total containment of waste waters by suitable landfill require even less land.

(27) Several commenters stated that it is impossible for multi-product plants to determine the contribution by intermediates and non-pesticide products to the final effluent load.

These regulations cover only the production of active ingredients and explicitly exclude the production of intermediates and non-pesticide products.

The data available suggest that pesticide production contributes to the effluent load in percentages less than that from non-pesticide production. While the available data are not sufficient to develop an exact correlation between production and effluent contribution, the Agency has assumed that the pesticide production wastes contribute to the total effluent load in the same ratio of pesticide production to the total plant production. In the absence of more detailed data, the Agency has concluded that this assumption is equitable and will not discriminate against multi-product plants. For example, if 10 pounds of BOD are discharged from a plant producing 30,000 pounds of total product, of which 10,000 pounds are pesticide active ingredients, the effluent attributed to active ingredient production would be 10/30x10 or 3.3 lb or 0.33 lb/1,000 lb production. This number must meet the effluent limitations.

If a particular facility can demonstrate that pesticide production actually contributes less effluent load than derived by use of production proportions and if the calculated effluent load exceeds the limitations, plant

submissions may be used to prove compliance for the pesticide production portion of the wastes.

(28) Several commenters objected to the use of statistical methods which assume a lognormal distribution. One commenter suggested that nonparametric statistical methods be used to determine variability factors.

In the revised analysis, the lognormal distribution was discarded and nonparametric methods, which do not assume a particular distributional form, were adopted. An extensive discussion of this procedure is presented in the Development Document.

(29) Several commenters objected to the averaging of variability factors from different plants and categories because of alleged differences among plants.

Averaging of variability factors is based on the mandate that the July 1, 1977, performance standards be determined by the average of the best plants. Nowhere do the commenters demonstrate that averaging variability factors is not statistically valid. One commenter claimed to show that statistically significant differences exist among variability factors through the use of a statistical hypothesis test. Documentation in support of the test, provided by the commenter in the form of a published journal article, states clearly that the results depend on the assumption of a normal population. This assumption is not justified for the effluent data and therefore the test applied by the commenter is inappropriate.

(30) Several commenters requested that data used in the analysis be provided for independent review.

Upon reviewing the comments, the Agency's statisticians reviewed the data. Many of the commenters' suggestions on the data analysis were used. All data used and the techniques employed are in the Development Doc-

ument and are also available for inspection in the EPA Public Information Unit.

(31) One commenter stated that data were arbitrarily discarded.

Data were excluded that represented start up modes and situations which are not representative of a well operated or designed treatment system.

(32) One commenter suggested that limitations be based on the largest value for discharge of pounds of pollutant per 1000 pounds of production.

This suggestion is not consistent with determining standards by computing the average of the best.

(33) One commenter stated, without attempting to justify his claim statistically, that three months of data from one plant was too short a time period to characterize the discharge.

It is desirable to have more data, but it is possible to obtain statistically adequate estimates of the variability factors with three months (i.e., 90 daily measurements) of data.

(34) Several commenters stated that the limitations were based on operational data from only a few plants.

The Agency has expanded the data base since the interim final regulations. This expanded data base includes data from the majority of the point source dischargers. The data used to derive the final limitations were taken from approximately one-third of the manufacturers who are direct dischargers.

(35) One commenter stated that guidelines should be based on "attainable concentration" rather than "percent removal".

A percent removal technique has not been used. The limitations are based on lb/1,000 lb. Due to dilution practiced in the industry, the use of "attainable concentration" would not control the total pounds of pollutant discharged.

(36) One commenter suggested that pesticide chemicals produced in small quantities such as experimental products be excluded from coverage under the regulations.

The final regulations do not cover the manufacture of active ingredients which are used solely in experimental pesticides.

(37) One commenter stated that by failing to concurrently promulgate BAT (Best Available Technology Economically Achievable) limitations, the EPA has prohibited plants from planning the required 1983 control technology.

EPA intends to propose BAT limitations by June 30, 1979 and to promulgate BAT limitations by December 31, 1979. The EPA will distribute draft copies of the Development Document well before the latter date to assure that affected parties will have adequate time to comply with the regulations.

Sec.

455.10 General definitions.

Subpart A—Organic Pesticide Chemicals Manufacturing Subcategory

Sec.

455.20 Applicability; description of the organic pesticide chemicals manufacturing subcategory.

455.21 Specialized definitions.

455.22 Effluent limitations guidelines representing the degree of effluent reduction attainable by the applica-

tion of the best practicable control technology currently available.

Subpart B—Metallo-Organic Pesticide Chemicals Manufacturing Subcategory

Sec.

455.30 Applicability; description of the metallo-organic pesticide chemicals manufacturing subcategory.

455.31 Specialized definitions.

455.32 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart C—Pesticide Chemicals Formulating and Packaging Subcategory

Sec.

455.40 Applicability; description of the pesticide chemicals formulating and packaging subcategory.

455.41 Specialized definitions. [Reserved]

455.42 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

AUTHORITY: Secs. 301 and 304. Federal Water Pollution Control Act, as amended (33 U.S.C. 1311, 1314, 86 Stat. 816 et seq. ("the Act").

§ 455.10 General definitions.

As used in this part:

(a) (1) "Pesticide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

(b) "Active ingredient" means an ingredient of a pesticide which is intended to prevent, destroy, repel, or mitigate any pest.

(c) "Pesticide chemicals" means the sum of all active ingredients manufactured at each facility covered by this part.

(d) "Pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except virusus, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1) of Public Law 94-140, Federal Insecticide, Fungicide and Rodenticide Act.

(e) Except as provided in this regulation, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this part.

Subpart A—Organic Pesticide Chemicals Manufacturing Subcategory

§ 455.20 Applicability; description of the organic pesticide chemicals manufacturing subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of organic active ingredients, excluding the following: Allethrin, Benzyl Benzoate, Biphenyl, Bisethylxanthogen, Chlorophacinone, Coumafuryl, Dimethyl Phthalate, Diphacinone, Endothall Acid, EXD (Herbisan), Gibberellic Acid, Glyphosate, Methoprene, Naphthalene Acetic Acid, Phenylphenol, Piperonyl Butoxide, Propargite, 1, 8 Naphthalic Anhydride, Quinomethionate, Resmethrin, Rotenone, Sulfoxide, Sodium Phenylphenate, Triazine compounds (both symmetrical and asymmetrical), and Warfarin and similar anticoagulants. The intermediates used to manufacture the active ingredients and active ingredients used

solely in experimental pesticides are excluded from coverage in this subpart. Insecticidal pathogenic organisms such as Bacillus thuringiensis, insect growth hormones, plant extracts such as pyrethrinis, sex attractants and botanicals such as Rotenone are also excluded from coverage in this subpart.

§ 455.21 Specialized definitions.

(a) "Organic active ingredients" means carbon-containing active ingredients used in pesticides, excluding metallo-organic active ingredients.

§ 455.22 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is possible, however, that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

The following limitations establish the quantity or quality of pollutants or pollutant properties controlled by this paragraph which may be discharged from the manufacture of organic active ingredients by a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

	Effluent limitations	
Effluent characteristic	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
COD	13.000	9.0000
BOD5	7.400	1.6000
TSS	6.100	1.8000
Pesticide chemicals	.010	.0018
pH	(1)	(1)

[1] Within the range 6.0 to 9.0.

Note:—Metric units: Kilogram/1.000 kg of pesticide chemicals; English units: Pound/1.000 lb of pesticide chemicals.

Subpart B—Metallo-Organic Pesticide Chemicals Manufacturing Subcategory

§ 455.30 Applicability; description of the metallo-organic pesticide chemicals manufacturing subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of metallo-organic active ingredients containing mercury, cadmium, arsenic, or copper. The manufacture of intermediates used to manufacture the active ingredients are excluded from coverage by this subpart.

§ 455.31 Specialized definitions.

(a) "Metallo-organic active ingredients" means carbon containing active ingredients containing one or more metallic atoms in the structure.

§ 455.32 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is possible, however, that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in

the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

The following limitations establish the quantity or quality of pollutants or pollutant properties controlled by this paragraph which may be discharged from the manufacture of metallo-organic active ingredients by a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available: There shall be no discharge of process waste water pollutants to navigable waters.

Subpart C—Pesticide Chemicals Formulating and Packaging Subcategory

§ 455.40 Applicability; description of the pesticide chemicals formulating and packaging subcategory.

The provisions of this subpart are applicable to discharges resulting from all pesticide formulating and packaging operations.

§ 455.41 Specialized definitions.

[Reserved]

§ 455.42 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is possible, however, that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

The following limitations establish the quantity or quality of pollutants or pollutant properties controlled by this paragraph from the formulation and packaging of pesticides by a point source subject to the provisions of

this paragraph after application of the best practicable control technology currently available: There shall be no discharge of process waste water pollutants to navigable waters.

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Supreme Court, U.S.
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No. 79-485

In the Supreme Court of the United States

OCTOBER TERM, 1979

ELI LILLY AND COMPANY, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR,
ENVIRONMENTAL PROTECTION AGENCY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The decision of the court of appeals (Pet. App. 1a-53a) is reported at 598 F. 2d 637. The decision of the Administrator of the Environmental Protection Agency is published at 43 Fed. Reg. 17776 (1978) (Pet. App. 59a-109a). The interim final regulations are published at 41 Fed. Reg. 48088 (1976).

JURISDICTION

The judgment of the court of appeals was entered on May 7, 1979 (Pet. App. 54a-58a). A petition for rehearing was denied on June 25, 1979. The petition for a writ of certiorari was filed on September 21, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether Section 4 of the Administrative Procedure Act, 5 U.S.C. 553, requires EPA to provide an additional opportunity to comment on final regulations because those regulations differ to some extent from interim final regulations, as a result of changes made primarily in response to comments and data submitted during the comment period.

2. Whether the court of appeals applied the proper standard in reviewing the determinations of the Administrator.

STATEMENT

The Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*, establishes as a "national goal that the discharge of pollutants into the navigable waters be eliminated by 1985." 33 U.S.C. 1251(a)(1). To achieve that goal, polluters are required to limit discharges in accordance with "the best practicable control technology currently available" ("BPT") by July 1, 1977, and, by July 1983, in accordance with "the best available technology economically achievable ("BAT"). 33 U.S.C. 1311(b)(1)(A), (2)(A).

This case involves regulations that establish effluent limitations for the pesticide manufacturing industry in accordance with BPT. Development of these regulations began in 1976 with the distribution for comment of draft technical and support documents to interested parties, including petitioner. 41 Fed. Reg. 48088, 48093 (1976). On November 1, 1976, EPA published regulations in interim final form[1] and responded in detail to the

[1]This procedure was followed because of an order requiring the agency to adopt regulations effective immediately upon publication. *Natural Resources Defense Council* v. *Train*, 6 E.R.C. 1033 (D. D.C. 1973).

comments submitted on these materials. 41 Fed. Reg. 48088, 48093-48096 (1976). These comments had identified subcategorization of the industry, treatability of pesticides, and the need for more industry data as important issues. *Id.* at 48093-48094. Two volumes of materials explaining the derivation of the regulations were made available, and EPA specifically requested additional comments and data. *Id.* at 48088.

The interim regulations divided the pesticides industry into five subcategories: three governing organic pesticide manufacture (organo-nitrogen, organo-phosphorus, and halogenated organic pesticides) and one subcategory each for metallo-organic pesticide manufacture and pesticide formulation and packaging. *Id.* at 48089-48091. Effluent limits for specific pollutants were established based on the application of technologies for pesticide removal that included hydrolysis or carbon sorption. *Id.* at 48094. In developing these interim limitations, EPA utilized all the information that it was able to generate and collect. *Id.* at 48089. Data from seven plants were used in deriving the interim regulations (Pet. App. 13a).

The agency received extensive comments on the interim regulations, particularly regarding the subcategorization of organic pesticides (Pet. App. 87a-89a). The comments urged, *inter alia*, that the agency consider the extent to which pesticides are subject to treatment in developing a subcategorization plan, suggesting that the record did not support the significantly different limits assigned to the three proposed organic manufacturing subcategories (Pet. App. 87a-89a). Generally, the industry urged the creation of more subcategories (Pet. App. 9a, 89a). In response to these comments, the agency thoroughly reexamined its data base, expanded its literature review, and inspected all plants treating

pesticides with the recommended carbon sorption and hydrolysis systems, including two facilities that had not supplied data for the interim regulations (see Pet. App. 15a-16a).

Additional data were collected from pesticides manufacturers, including petitioner.[2] Petitioner employs a carbon treatment system for wastewater from its process for the manufacture of trifluralin, an organo-nitrogen pesticide. That process was analyzed both by EPA's contractor, ESE, and by petitioner. The trifluralin effluent data obtained by ESE were made available to petitioner (Pet. 21 n.9). Petitioner discovered significant differences between its own and ESE's analysis of presumably identical samples taken from the plant (Pet. 20-21 n.9). Petitioner informed the agency that ESE's figures were substantially higher than its own (demonstrating less effective treatment), but the discrepancy was not explained (Pet. App. 24a-25a). In developing the final rule, the agency used the higher ESE effluent values for petitioner's plant, thereby making the final discharge limitations less stringent than if petitioner's figures had been used (*ibid.*).

The final regulations were promulgated on April 25, 1978 (Pet. App. 59a-109a). Some changes from the interim regulations were made, primarily as a result of industry comments (Pet. App. 6a). With regard to subcategorization, the agency found, as many commenters had urged, that there should not be three different organic pesticide subcategories and that all organic pesticide manufacturing plants could treat their

[2]Industry provided 95% of the data used in calculating the final limitations (Pet. App. 16a).

pesticides to achieve the same effluent level (Pet. App. 64a). Accordingly, the three subcategories were consolidated into one organic pesticide category (Pet. App. 63a-64a).

Overall, the final limitations were more stringent than the interim ones for some producers and less stringent for others (Pet. App. 5a). For petitioner's trifluralin plant, the final limitations are lower than the interim ones, but, as petitioner notes (Pet. 21 n.9), they are higher than petitioner's actual discharge as observed either by ESE or petitioner. After the final regulations were issued, one company petitioned the agency for reconsideration alleging, *inter alia*, that analytical techniques were unavailable to detect many pesticides at the levels set. On reconsideration of the record, the agency limited the applicability of the final regulations to 49 of several hundred pesticides (Pet. App. 5a).

Eleven pesticide manufacturers, including petitioner, brought suit to challenge the regulations. The court of appeals held that petitioner had a fair opportunity to present its views on the issues involved in the organic pesticide rulemaking (Pet. App. 6a-16a). Regarding subcategorization, the court found that the consolidation of the subcategories was suggested by, and in part a logical outgrowth of, industry's comments (Pet. App. 9a, 34a-35a). Similarly, the court found that a fair opportunity to comment on the issue of pesticide treatability had been presented (Pet. App. 11a-12a).

With respect to the data base supporting the final regulations, the court noted that 82% of the data was from the seven facilities that had formed the basis for the interim regulations and that all relevant information concerning those facilities had been disclosed and subject to comment (Pet. App. 13a-14a). The court also found

that the treatment technologies at the two additional facilities considered in the final regulation conformed to EPA's "fully disclosed model technology" and were similar to those used at the other plants (Pet. App. 15a). Finally, the use of the additional data from those two plants rendered the final limitations less stringent (Pet. App. 15a-16a). In sum, the court of appeals concluded that the industry was provided with an adequate opportunity to comment on the regulations (Pet. App. 11a-12a).

The court of appeals remanded the case to EPA for the limited purposes of reconsidering discharge data from Olin Corporation's McIntosh, Alabama plant (Pet. App. 33a), and reconsidering the costs of meeting the metallo-organic pesticide limitation (Pet. App. 40-43a). The court retained jurisdiction of the case pending the action of the agency on remand (Pet. App. 52a-53a).

ARGUMENT

The decision of the court of appeals is correct and is not in conflict with any other court of appeals decision. Further review of this essentially fact bound case is unwarranted.

1. Petitioner contends (Pet. 10-13, 16-21) that it should be provided an opportunity to comment on the final pesticide limitations issued by EPA because the final rules differ from the interim final rules. It is well-established, however, that final regulations may differ from those proposed without triggering the need for a new comment period. See *American Frozen Food Institute* v. *Train*, 539 F. 2d 107, 134 (D.C. Cir. 1976); *International Harvester Co.* v. *Ruckelshaus*, 478 F. 2d 615, 632 (D.C. Cir. 1973); *American Iron and Steel Institute* v. *EPA*, 568 F. 2d 284, 293 (3d Cir. 1977);

South Terminal Corp. v. *EPA*, 504 F. 2d 646, 658-659 (1st Cir. 1974); *California Citizens Band Ass'n* v. *United States*, 375 F. 2d 43, 47-49 (9th Cir.), cert. denied, 389 U.S. 844 (1967). Petitioner nevertheless asserts that, in the particular circumstances of this case, it was deprived of an opportunity to comment.

The suggestion (Pet. 11-12, 20) is that because the agency relied partly on data submitted during the comment period, petitioner was deprived of an opportunity to comment.[3] After a thorough examination of the record, the court of appeals correctly found that none of the new data submitted raised any new issues for comment (Pet. App. 12a-16a). Seven of the nine plants used for collecting data were listed in the interim development document and 82% of the data points were derived from these plants (Pet. App. 12a-13a). Moreover, EPA's methodology was revealed to petitioner prior to the comment period and that methodology did not change (Pet. App. 14a; compare Pet. App. 69a-70a with 41 Fed. Reg. 48088, 48091 (1976)). The fact that the companies did not know during the comment period what the ultimate numbers would be did not restrict their ability to comment on the method used to collect data or how the data were used.

The principal change in the regulations that petitioner seeks to comment upon is the consolidation of the three interim organic pesticide subcategories that resulted in a lower effluent limitation for trifluralin (Pet. 19-21). Clearly, petitioner had an opportunity to comment on

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[3]Ironically, petitioner and the other ten petitioners below attacked the regulations substantively on the ground that EPA did not collect sufficient data (Pet. App. 12a n.11). In fact, the court of appeals found (Pet. App. 29a) that data difficulties in this area exist partly because "the industry is very reticent about revealing what it does (or could) know."

this issue. The agency's method of subcategorization was one of the industry's principal concerns with the draft and interim regulations. It was certainly foreseeable that the final subcategories would be different from the interim ones because the industry was "almost unanimous in condemning the three original subcategories" (Pet. App. 9a). One commenter presented a statistical analysis indicating that the three organic pesticide subcategories were indistinguishable from each other (*ibid.*). One repeated comment was the request that the three subcategories be treated more equitably (Pet. App. 10a). Thus, the actual result of a consolidation of the subcategories was a logical response to industry comments.

Petitioner contends (Pet. 19-21) that it has been particularly deprived of an opportunity to comment, as compared to the other 10 plaintiffs in the court of appeals, because it had no objection to the trifluralin limitations that were established in the interim regulations. This contention is without merit. Petitioner was aware that the limitations might be changed in the final regulations in response to comments. Petitioner had every opportunity to comment on what it thought to be a proper effluent limitation for trifluralin. There is no requirement that a party be dissatisfied with the numbers set forth in interim or proposed regulations in order to be eligible to comment on those regulations.[4] Moreover,

[4]Petitioner's suggestion (Pet. 19) that the court of appeals did not consider its individual contentions is without foundation. The court found that any divergence of EPA's data from petitioner's redounded to petitioner's benefit (Pet. App. 24a-25a, 31a) and that the claim that petitioner generated an untreated waste stream was "unconvincing" (Pet. App. 31a). Finally, as petitioner concedes (Pet. 19 & n.7), the court specifically stated that "[r]egulatory targets have no guarantee that proposed effluent limits, which they are capable of meeting, will stay the same. * * *[T]hose interest groups preferring looser limits are not the only ones whose comments are solicited."

petitioner does not suggest how it has been disadvantaged by its alleged inability to comment. EPA's use of ESE's higher figures resulted in a higher allowable discharge, to the benefit of petitioner (Pet. App. 25a). And, in any event, petitioner itself states that the discharge measured at its plant is within the effluent limitations set forth in the final regulations (Pet. 21 n.9). In sum, petitioner had ample notice and opportunity to comment in this rulemaking proceeding. It simply chose not to participate.

Finally, petitioner's assertion (Pet. 13-16) that this case conflicts with decisions of other courts of appeals is erroneous. The cases cited by petitioner (Pet. 13-16, 24-27) are quite different from this case because they involve unexplained, unsupported, or erroneous agency data or methodology, or the withholding of all data from the industry. In *National Crushed Stone Ass'n* v. *EPA*, 601 F. 2d 111, 117-119 (4th Cir. 1979),[5] the court found that the agency did not explain the reasoning involved in reaching its final figures and that the validity of the data relied upon was open to serious doubt. Here, the court found that the petitioners below did not establish that the data relied upon were open to serious question (Pet. App. 22a-26a). In *Weyerhaeuser Co.* v. *Costle*, 590 F. 2d 1011 (D.C. Cir. 1978), the court found that the agency's explanation of its methodology was inadequate, and the agency admitted that some of its computations were erroneous. 590 F. 2d at 1029-1030. In *United States* v. *Nova Scotia Food Products Corp.*, 568 F. 2d 240 (2d Cir. 1977), the Food and Drug Administration had concealed all of the research on which its rules were

[5]The government has filed a petition for a writ of certiorari, No. 79-770 (Nov. 15, 1979), to review the decision of the court of appeals in this case on an unrelated issue.

based, and the court specifically noted that it was not dealing with a case where the research data were supplied by the interested parties themselves. In *Portland Cement Ass'n* v. *Ruckelshaus*, 486 F. 2d 375 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974), the court remanded an emission standard because neither the test methodology nor the underlying data had been made available for comment. 486 F. 2d at 392-393.

2. Petitioner also contends that the court of appeals incorrectly engaged in de novo review (Pet. 22-24), substituted its own judgment for that of the agency (Pet. 26-27), and granted undue deference to the agency (Pet. 22-25). These contentions are without merit. Petitioners below challenged the procedures used by ESE in collecting data. EPA clearly concluded that the data were reliable (Pet. App. 22a), but the court of appeals went on to make its own review of the procedures. It considered the criticism in detail (see Pet. App. 23a-24a n.24), allowing three rounds of briefing memoranda (Pet. App. 16a), but found that the record evidenced "concern for careful procedure" (Pet. App. 23a) and that, although petitioners below had "combed the record" searching for laboratory errors (Pet. App. 22a), they had not established that EPA erred in relying on ESE data (Pet. App. 22a-26a). The court's careful and thorough review comports fully with the standards established in *Citizens To Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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v.

DOUGLAS M. COSTLE, ADMINISTRATOR,
ENVIRONMENTAL PROTECTION AGENCY

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

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REPLY BRIEF FOR PETITIONER ELI LILLY AND COMPANY

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REPLY BRIEF FOR PETITIONER ELI LILLY AND COMPANY

The petition for writ of certiorari presents three important questions. The first is the obligation of an agency under Section 4 of the Administrative Procedure Act, 5 U.S.C. § 553, to provide notice and opportunity for public comment before promulgating final regulations which differ substantially from the initial proposal and which are premised on a new and more extensive base of data. The second and third issues assume that notice and opportunity for comment is not required, and focus on the appropriate role of the reviewing court in such a case. Pet. at 2.

Respondent ("EPA") barely mentions the latter two issues relating to whether the First Circuit impermissibly substituted its judgment for that of EPA contrary to this Court's decision in *Federal Power Commission* v. *Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 333-34 (1976). EPA addresses just one of the numerous instances in which the First Circuit substituted its judgment for that of the agency: the First Circuit's conclusion, after an independent *de novo* review of the record, that petitioners had not carried their heavy burden of persuading the First Circuit that critical data reported by EPA's contractor (ESE) were invalid. Resp. Br. at 10.

EPA here seeks to convey the impression that it reviewed the ESE data and concluded that they were valid and that the First Circuit's independent *de novo* review was the result of unnecessary judicial prudence. Resp. Br. at 10. EPA did not make, and could not have made, a determination as to the reliability of the ESE data because the laboratory documents necessary for that determination were not turned over to EPA by ESE until after oral argument before the First Circuit. 598 F.2d at 646; Pet. App. A, 16a. The First Circuit also found the briefs and supplemental memorandum of agency counsel to be an inadequate explanation of the technical and scientific issues raised by the petitioners. *Id.* at 649; Pet. App. A., 22a.

It was in the *absence of any EPA determination* on this and other central issues that the First Circuit proceeded to substitute its judgment for that of EPA by engaging in an independent *de novo* review of the record or by making "assumptions" that EPA had rationally resolved issues when there was no evidence in the record that EPA had even considered the issues.

EPA concludes that the First Circuit's mode of review "comports fully with the standards established in *Citizens To Preserve Overton Park* v. *Volpe*, 401 U.S. 402

(1971)." Resp. Br. at 10. In *Overton Park*, the Court established a standard of judicial deference to judgments made by the agency in the administrative process because a contrary standard would result in the substitution of the reviewing court's judgment for that of the agency. The Court cautioned that agency judgments made outside of the usual administrative process—for example, additional findings requested by a reviewing court—should not be accorded that deference. 401 U.S. at 420. Here there were no agency judgments on the critical issues to which the First Circuit could defer.[1] The First Circuit, contrary to the Court's decision in *Transcontinental Gas Pipe Line*, simply injected itself into the administrative process by substituting its judgment for that of EPA.

The First Circuit placed itself in the position of substituting its judgment for that of EPA by deciding to review the regulations on the basis of a record incompletely tested by exposure to public comment under the APA. EPA's argument, in response to the first issue presented by the petition, that it complied with the APA appears principally aimed at creating the illusion that the notice-and-comment issue is "fact bound". Resp. Br. at 5.[2]

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[1] Eli Lilly does not construe EPA's argument as suggesting that a reviewing court should accord judicial deference to factual arguments made for the first time by agency counsel in briefs. Any such suggestion of judicial deference to the *post hoc* rationalizations of agency counsel would be contrary to decisions of this Court and the courts of appeal. *E.g.*, *Burlington Truck Lines* v. *United States*, 371 U.S. 156, 168-69 (1962); *Dry Color Manufacturers' Ass'n* v. *Department of Labor*, 486 F.2d 98, 104 n. 8 (3d Cir. 1973).

[2] In several instances, EPA includes misleading statements of the facts. For example, EPA indicates that Eli Lilly stated that its waste water discharge complies with the final regulations. Resp. Br. at 9. Eli Lilly has made no such statement. *See* Pet. at 20-21, n. 9. As pointed out by Eli Lilly, the First Circuit rejected the argument that the ESE data excluded waste water which bypassed Eli Lilly's carbon system because of the ambiguity of the

Quite to the contrary, this case presents a clear issue of law on which the decision of the First Circuit is in conflict with decisions in the Second, Fourth, and District of Columbia Circuits.[3] EPA made major changes in the regulations and made those changes based upon its assessment of a greatly expanded base of data. EPA emphasized these "major changes" and how its "expanded data base" had led it to the critical inferences underlying the major changes in the regulations. Pet. App. C., 63a-67a, 87a-89a; Pet. at 10-11.[4]

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record before it. 598 F.2d at 653; Pet. App. A, 31a. Had EPA issued a notice for further public comment on its expanded data base and indicated that it planned to use the Eli Lilly data as a base for substantially amending the first-stage regulations (rather than using the data in connection with future second-stage regulations as Eli Lilly understood), Eli Lilly would have had an opportunity to clarify the record. Pet. at 20-21, n. 9.

[3] EPA seeks to distinguish *National Crushed Stone Ass'n* v. *Environmental Protection Agency*, 601 F.2d 111 (4th Cir. 1979), petition for cert. filed (No. 79-770, Nov. 15, 1979), on the ground that the undisclosed data in this case "were not open to serious question." Resp. Br. at 9. EPA is in error. The sole difference between this case and *National Crushed Stone* is that the Fourth Circuit, upon determining that important data had not been subject to public comment, remanded the regulations to EPA for further consideration in accordance with the APA. The First Circuit, in contrast, held that the APA did not require remand and engaged in a "partial and facial" independent review of the record leading to an uncertain conclusion as to the validity of the data. 598 F.2d at 649-50; Pet. App. 23a-24a. In discussing *Weyerhauser Corp.* v. *Costle*, 590 F.2d 1011 (D.C. Cir. 1978), EPA overlooks, as did the First Circuit, the fact that the District of Columbia Circuit specifically held that the Agency had not complied with the APA because certain important conclusions reached by EPA "must be validated, if at all, by reference . . . to certain data . . . obtained by the Agency after the opportunity for public comment had lapsed . . . ." *Id.* at 1030.

[4] The table in which Eli Lilly illustrated the magnitude of the change from interim final to final regulations (Pet. at 11) contains a typographical error. The reduction in the daily maximum effluent limitation for pesticides from the interim final to final regulations was 37 percent rather than 47 percent. The reduction in the 30-day average is correctly stated as 75 percent.

The First Circuit held that public notice and an opportunity to comment on the new data and on the inferences which EPA drew from that new data are unimportant and not required by Section 4 of the APA. 598 F.2d at 644-45; Pet. App. A, 12a-13a, 15a.

That decision of the First Circuit is incorrect and this Court should grant the petition for certiorari in order to resolve the conflict of decisions among the courts of appeals and provide guidance to the courts of appeals and to the administrative agencies on important issues of administrative law.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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